



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

Directorate General of Foreign Trade, Delhi / विदेश व्यापार महानिदेशालय, दिल्ली

VANIJYA BHAWAN, AKBAR ROAD, NEW DELHI / वाणिज्य भवन, अकबर रोड, नई दिल्ली

Email Office : dgft@nic.in , Phone Office : 011-23062777

## (DES - III SECTION)

## MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Dec/202223/15

DATED: 29/12/2022

Please Note

- I. For information of exporters, Norms Committee - III handles all cases pertaining to fixation/ratification of norms for Export Products falling under ITC (HS) Chapter 29, 30 .Communications in respect of cases/pertaining to NC- III may be sent to email address: nc3.dgft@nic.in
- II. The Norms Committee has taken decision only with respect to technical aspect/wastage norms. While redeeming the applications, RAs should check that the applicant has fulfilled all requirements as prescribed in policy/procedure including those in Policy Circulars issued from time to time or any other provisions under FTP/HBP for EODC.
- III. Wherever the Committee has fixed Norms, the concerned RA may ensure that AA is issued on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less.

Meeting No. NC/3/MEET/Dec/202223/15 dated 29/12/2022 of Norms Committee - III for the year 2022-23 was held on 29/12/2022 under the Chairmanship of Rajiv Soni ,Joint DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2015-20.

The following members were present in the meeting:-

| S.No. | Name and Designation of Representatives  | Department |
|-------|------------------------------------------|------------|
| 1     | AJAY KUMAR,Deputy Director               | DGFT(HQ)   |
| 2     | NAND Lal,Technical Consultant            | DPIIT      |
| 3     | DINESHNARAIN MATHUR,Technical Consultant | DGFT       |

**Case Details and Decision(s):**

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| Case No.                                                                                                                                                                                                                                                                                                                                                                            | 1 / NC/3/MEET/Dec/202223/15                 |
| Case Status                                                                                                                                                                                                                                                                                                                                                                         | Case Deferred                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                          | BIO-GEN EXTRACTS PRIVATE LIMITED            |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                             | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                      | HQRNORM APPLY 00003012AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                      | NA                                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                 | NA                                          |
| <p>Norms Committee Decision:</p> <p>The Committee considered the request of firm for fixation of adhoc norms and it was observed that as per COA, details of import and export items are not different and also the process given is confusing.</p> <p>Hence, it was decided to call the firm for attending <b>Personal Hearing</b> before Norms Committee to explain its case.</p> |                                             |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                     | 2 / NC/3/MEET/Dec/202223/15                 |         |                                       |             |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                  | Case Approved                               |         |                                       |             |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                   | INDIA GLYCOLS LIMITED                       |         |                                       |             |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |         |                                       |             |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                               | HQRNORM APPLY 00004452AM23                  |         |                                       |             |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                               | NA                                          |         |                                       |             |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                          | NA                                          |         |                                       |             |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                    |                                             |         |                                       |             |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Nov/202223/12 dated 18.11.2022</b> against advance authorization No. <b>0511011991 dated 20.04.2022</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |         |                                       |             |
|                                                                                                                                                                                                                                                                                                                                                                                                              |                                             |         |                                       |             |
| Export product                                                                                                                                                                                                                                                                                                                                                                                               | Qty.                                        | Sl. No. | Import items                          | Qty.        |
| Mono Ethylene Glycol (MEG)                                                                                                                                                                                                                                                                                                                                                                                   | 1 kg                                        | 1       | Denatured Ethyl Alcohol               | 1.123 kg    |
|                                                                                                                                                                                                                                                                                                                                                                                                              |                                             | 2       | Silver Catalyst (Activity 17% to 18%) | 0.000228 kg |
|                                                                                                                                                                                                                                                                                                                                                                                                              |                                             | 3       | Alumina Catalyst                      | 0.000362 kg |

RA concerned may take further necessary action as per above decision of NC.

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| Case No.                                                                                                                                                                                                                                                                                                                                                                            | 3 / NC/3/MEET/Dec/202223/15                 |
| Case Status                                                                                                                                                                                                                                                                                                                                                                         | Case Deferred                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                          | BIO-GEN EXTRACTS PRIVATE LIMITED            |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                             | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                      | HQRNORM APPLY 00003010AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                      | NA                                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                 | NA                                          |
| <p>Norms Committee Decision:</p> <p>The Committee considered the request of firm for fixation of adhoc norms and it was observed that as per COA, details of import and export items are not different and also the process given is confusing.</p> <p>Hence, it was decided to call the firm for attending <b>Personal Hearing</b> before Norms Committee to explain its case.</p> |                                             |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                            | 4 / NC/3/MEET/Dec/202223/15                 |
| Case Status                                                                                                                                                                                                                                                                                                                                                                         | Case Deferred                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                          | BIO-GEN EXTRACTS PRIVATE LIMITED            |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                             | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                      | HQRNORM APPLY 00003011AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                      | NA                                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                 | NA                                          |
| <p>Norms Committee Decision:</p> <p>The Committee considered the request of firm for fixation of adhoc norms and it was observed that as per COA, details of import and export items are not different and also the process given is confusing.</p> <p>Hence, it was decided to call the firm for attending <b>Personal Hearing</b> before Norms Committee to explain its case.</p> |                                             |

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| Case No.                | 5 / NC/3/MEET/Dec/202223/15                 |
| Case Status             | Case Deferred                               |
| Party Name              | CORPORATE CHANNELS (INDIA) PVT. LTD         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |

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|------------------------------|---------------------------|
| HQ File Number               | HQRNORM REVIW00002028AM23 |
| RA File Number               | 132404000019 AM14         |
| Licence No and Date          | 1310044179/29/08/2013     |
| Norms Committee Decision:    |                           |
| Deferred for comments of TE. |                           |

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|------------------------------|---------------------------------------------|
| Case No.                     | 6 / NC/3/MEET/Dec/202223/15                 |
| Case Status                  | Case Deferred                               |
| Party Name                   | PARAMOUNT AROMACHEM PRIVATE LIMITED         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM REVIW00001869AM23                   |
| RA File Number               | 052404000399 AM17                           |
| Licence No and Date          | 0510400599/02/12/2016                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                     | 7 / NC/3/MEET/Dec/202223/15                 |
| Case Status                  | Case Deferred                               |
| Party Name                   | NATURAL HERBS & FORMULATIONS                |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM REVIW00004230AM23                   |
| RA File Number               | 612404000001 AM18                           |
| Licence No and Date          | 6110001419/13/04/2017                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                     | 8 / NC/3/MEET/Dec/202223/15                 |
| Case Status                  | Case Deferred                               |
| Party Name                   | PARAMOUNT AROMACHEM PRIVATE LIMITED         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM REVIW00001867AM23                   |
| RA File Number               | 052404000008 AM18                           |
| Licence No and Date          | 0510402246/18/04/2017                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                     | 9 / NC/3/MEET/Dec/202223/15                 |
| Case Status                  | Case Deferred                               |
| Party Name                   | NATURAL HERBS & FORMULATIONS                |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM REVIW00004226AM23                   |
| RA File Number               | 612404000002 AM18                           |
| Licence No and Date          | 6110001452/18/08/2017                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                     | 10 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | PARAMOUNT AROMACHEM PRIVATE LIMITED         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM REVIW00001870AM23                   |
| RA File Number               | 052404000297 AM18                           |
| Licence No and Date          | 0510404439/31/10/2017                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                     | 11 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | NATURAL HERBS & FORMULATIONS                |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM REVIW00004092AM23                   |
| RA File Number               | 612404000004 AM18                           |
| Licence No and Date          | 6110001484/16/01/2018                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                | 12 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Deferred                               |
| Party Name              | KAIRAV CHEMOFARBE INDUSTRIES LIMITED        |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM REVIW00160008AM22                   |

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|------------------------------|-----------------------|
| RA File Number               | 039404000838 AM18     |
| Licence No and Date          | 0310818810/31/01/2018 |
| Norms Committee Decision:    |                       |
| Deferred for comments of TE. |                       |

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| Case No.                     | 13 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | AUROBINDO PHARMA LTD                        |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM REVIW00001184AM23                   |
| RA File Number               | 092404000181 AM19                           |
| Licence No and Date          | 0910066442/11/07/2018                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                                                                                                                                                                                                                 | 14 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                                                                                                                                                                              | Case Approved                               |
| Party Name                                                                                                                                                                                                               | AUROBINDO PHARMA LTD                        |
| Meeting Number and Date                                                                                                                                                                                                  | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                           | HQRNORM REVIW00001185AM23                   |
| RA File Number                                                                                                                                                                                                           | 092404000345 AM19                           |
| Licence No and Date                                                                                                                                                                                                      | 0910066762/25/10/2018                       |
| Norms Committee Decision:                                                                                                                                                                                                |                                             |
| The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |
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|  |  | 4 | Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)                       | 89.76 kg |
|  |  | 5 | Potassium Clavulanate diluted with Microcrystalline Cellulose (1:1) / Clavulanate Potassium + Avicel [in Active Base] | 10200 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 15 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | AUROBINDO PHARMA LTD                        |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM REVIW00001186AM23                   |
| RA File Number          | 092404000386 AM19                           |
| Licence No and Date     | 0910066874/20/11/2018                       |

**Norms Committee Decision:**

The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export Product                                                                                                                                                                                | Qty.              | Sl. No. | Import Items                                                                                     | Qty.        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---------|--------------------------------------------------------------------------------------------------|-------------|
| AMOXYCILLIN AND CLAVULANATE POTASSIUM TABLETS 1000 MG([The Relevant Bulk Drug content in the export product is Amoxycillin Trihydrate 87500 Kgs and Clavulanate Potassium + Avicel 12500 Kgs) | 100000000 Numbers | 1       | 6-APA                                                                                            | 50694.00 kg |
|                                                                                                                                                                                               |                   | 2       | Methanol                                                                                         | 3275.50 kg  |
|                                                                                                                                                                                               |                   | 3       | Methyl d-(-)-4-hydroxy-phenylglycinate OR D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester] | 42982.80 kg |
|                                                                                                                                                                                               |                   | 4       | Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)  | 196.35 kg   |
|                                                                                                                                                                                               |                   | 5       | Potassium Clavulanate diluted with                                                               | 12750 kg    |

|                                                                             |  |  |                                                                                                   |  |
|-----------------------------------------------------------------------------|--|--|---------------------------------------------------------------------------------------------------|--|
|                                                                             |  |  | Microcrystalline Cellulose (1:1) / Activity<br>Clavulanate Potassium + Avicel [in Active<br>Base] |  |
| RA concerned may take further necessary action as per above decision of NC. |  |  |                                                                                                   |  |

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|------------------------------|---------------------------------------------|
| Case No.                     | 16 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | TIDE INDUSTRIES                             |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM REVIW00001539AM23                   |
| RA File Number               | 342404000083 AM20                           |
| Licence No and Date          | 3410045200/10/06/2019                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                     | 17 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | JINDAL DRUGS PRIVATE LIMITED                |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM REVIW00405134AM22                   |
| RA File Number               | 039404000005 AM21                           |
| Licence No and Date          | 0310835906/25/04/2020                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|---------------------------|---------------------------------------------|
| Case No.                  | 18 / NC/3/MEET/Dec/202223/15                |
| Case Status               | Case Deferred                               |
| Party Name                | JINDAL DRUGS PRIVATE LIMITED                |
| Meeting Number and Date   | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number            | HQRNORM REVIW00405090AM22                   |
| RA File Number            | 039404000003 AM21                           |
| Licence No and Date       | 0310835903/25/04/2020                       |
| Norms Committee Decision: |                                             |

Deferred for comments of TE.

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| Case No.                     | 19 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | KUMAR ORGANIC PRODUCTS LIMITED              |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM REVIW00000645AM23                   |
| RA File Number               | 072404000030 AM21                           |
| Licence No and Date          | 0710116410/01/05/2020                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                     | 20 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | STERILE INDIA PRIVATE LIMITED               |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM REVIW00000568AM23                   |
| RA File Number               | 052404000295 AM21                           |
| Licence No and Date          | 0510415273/21/09/2020                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                                                                                                                                                                                                               | 21 / NC/3/MEET/Dec/202223/15                |  |  |  |  |
| Case Status                                                                                                                                                                                                            | Case Approved                               |  |  |  |  |
| Party Name                                                                                                                                                                                                             | ZYDUS LIFESCIENCES LIMITED                  |  |  |  |  |
| Meeting Number and Date                                                                                                                                                                                                | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |  |  |  |  |
| HQ File Number                                                                                                                                                                                                         | HQRNORM REVIW00003412AM23                   |  |  |  |  |
| RA File Number                                                                                                                                                                                                         | 08AA04004845 AM21                           |  |  |  |  |
| Licence No and Date                                                                                                                                                                                                    | 0811000109/18/12/2020                       |  |  |  |  |
| Norms Committee Decision:                                                                                                                                                                                              |                                             |  |  |  |  |
| The Committee considered the request of firm for review of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |  |  |  |  |
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|---|--------------------------------------------------------------------------------------------------------------------------------|----------|---|-----------------------|----------------------------|
| 1 | ISOTRETINOIN CAPSULES USP 10 MG (ISOTRETINOIN CAPSULES USP 10 MG (ACTIVE INGREDIENT: ISOTRETINOIN USP - NET WT. 11.249 KGS.))  | 1 Number | 1 | ISOTRETINOIN USP      | 10.2 mg /<br>10 mg capsule |
|   |                                                                                                                                |          | 2 | GELATIN NF            | 375 mg                     |
|   |                                                                                                                                |          | 3 | GLYCERIN USP          | 191 mg                     |
|   |                                                                                                                                |          | 4 | ISOPROPYL ALCOHOL USP | 200 mg /<br>10 mg capsule  |
| 2 | ISOTRETINOIN CAPSULES USP 20 MG (ISOTRETINOIN CAPSULES USP 20 MG (ACTIVE INGREDIENT: ISOTRETINOIN USP - NET WT. 107.998 KGS.)) | 1 Number | 1 | ISOTRETINOIN USP      | 20.4 mg /<br>20 mg capsule |
|   |                                                                                                                                |          | 2 | GELATIN NF            | 468 mg                     |
|   |                                                                                                                                |          | 3 | GLYCERIN USP          | 239 mg                     |
|   |                                                                                                                                |          | 4 | ISOPROPYL ALCOHOL USP | 250 mg /<br>20 mg capsule  |
| 3 | ISOTRETINOIN CAPSULES USP 30 MG (ISOTRETINOIN CAPSULES USP 30 MG (ACTIVE INGREDIENT: ISOTRETINOIN USP - NET WT. 161.995 KGS.)) | 1 Number | 1 | ISOTRETINOIN USP      | 30.6 mg /<br>30 mg capsule |
|   |                                                                                                                                |          | 2 | GELATIN NF            | 562 mg                     |
|   |                                                                                                                                |          | 3 | GLYCERIN USP          | 287 mg                     |
|   |                                                                                                                                |          | 4 | ISOPROPYL ALCOHOL USP | 300 mg /<br>30 mg capsule  |
| 4 | ISOTRETINOIN CAPSULES USP 40 MG (ISOTRETINOIN CAPSULES USP 40 MG (ACTIVE INGREDIENT: ISOTRETINOIN USP - NET WT. 161.995 KGS.)) | 1 Number | 1 | ISOTRETINOIN USP      | 40.8 mg /<br>40 mg capsule |
|   |                                                                                                                                |          | 2 | GELATIN NF            | 562 mg                     |

|  |                                           |  |   |                       |                           |
|--|-------------------------------------------|--|---|-----------------------|---------------------------|
|  | ISOTRETINOIN USP - NET WT. 359.993 KGS.)) |  | 3 | GLYCERIN USP          | 287 mg                    |
|  |                                           |  | 4 | ISOPROPYL ALCOHOL USP | 300 mg /<br>40 mg capsule |

RA concerned may take further necessary action as per above decision of NC.

|                                                                                                                                                                                                                                                                                                                                                                                     |                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                            | 22 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                         | Case Deferred                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                          | STERILE INDIA PRIVATE LIMITED               |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                             | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                      | HQRNORM REVIW00000419AM23                   |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                      | 05AA04037727 AM21                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                 | 0511001580/08/03/2021                       |
| <p>Norms Committee Decision:</p> <p>The Committee considered the request of firm for fixation of adhoc norms and it was observed that the details furnished by the firm was incomplete and also the DML was not given for Approved Composition.</p> <p>Hence, it was decided to call the firm for attending <b>Personal Hearing</b> before Norms Committee to explain its case.</p> |                                             |

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| Case No.                                                                                                                                                                                                                 | 23 / NC/3/MEET/Dec/202223/15                |  |  |  |
| Case Status                                                                                                                                                                                                              | Case Approved                               |  |  |  |
| Party Name                                                                                                                                                                                                               | INDOCO REMEDIES LIMITED                     |  |  |  |
| Meeting Number and Date                                                                                                                                                                                                  | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |  |  |  |
| HQ File Number                                                                                                                                                                                                           | HQRNORM REVIW00003465AM23                   |  |  |  |
| RA File Number                                                                                                                                                                                                           | 03AA04002955 AM22                           |  |  |  |
| Licence No and Date                                                                                                                                                                                                      | 0311003171/20/04/2021                       |  |  |  |
| Norms Committee Decision:                                                                                                                                                                                                |                                             |  |  |  |
| The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |  |  |  |
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| Ketotifen Fumarate ophthalmic solution (5ml Bottle )((Each ml. Contains: Ketotifen(0.025 percentage) Antihistamine) (Equivalent to Ketotifen Fumarate 0.035 percentage ) = 1.750 mg per bottle of 5ml.) (Net Weight in Export Products is : 787.5 GRAM )) | 1 Number | 1 | Ketotifen Fumarate | 1.785 mg                       |
|                                                                                                                                                                                                                                                           |          | 2 | Bottle             | Relevant as per packing policy |
|                                                                                                                                                                                                                                                           |          | 3 | Cap                | Relevant as per packing policy |
|                                                                                                                                                                                                                                                           |          | 4 | Dropper            | Relevant as per packing policy |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 24 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | ZYDUS LIFESCIENCES LIMITED                  |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM REVIW00003410AM23                   |
| RA File Number          | 08AA04001824 AM22                           |
| Licence No and Date     | 0811001352/28/04/2021                       |

## Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and it was decided to revise adhoc norms as under:

| Sl. No. | Export Product                                                                                                                   | Qty.               | Sl. No. | Import items                                                     | Qty.       |
|---------|----------------------------------------------------------------------------------------------------------------------------------|--------------------|---------|------------------------------------------------------------------|------------|
| 1       | BUSPIRONE<br>HYDROCHLORIDE TABLETS<br>USP 5 MG((ACTIVE<br>INGREDIENT : BUSPIRONE<br>HYDROCHLORIDE USP -<br>NET WT. 22.994 KGS.)) | 4598800<br>Numbers | 1       | BUSPIRONE HYDROCHLORIDE USP                                      | 23.454 kg  |
|         |                                                                                                                                  |                    | 2       | LACTOSE MONOHYDRATE NF/PH EUR                                    | 224.573 kg |
|         |                                                                                                                                  |                    | 3       | MICRO CRYSTALLINE<br>CELLULOSE NF/IP/BP/PH EUR<br>(AVICEL PH102) | 76.65 kg   |
|         |                                                                                                                                  |                    | 4       | SODIUM STARCH GLYCOLATE NF                                       | 13.80 kg   |

|   |                                                                                                                                         |                     |   |                                                                  |             |
|---|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------|---|------------------------------------------------------------------|-------------|
|   |                                                                                                                                         |                     | 5 | COLLOIDAL SILICON DIOXIDE NF                                     | 3.449 kg    |
|   |                                                                                                                                         |                     | 6 | MAGNESIUM STEARATE PH<br>EUR/NF/JP                               | 3.449 kg    |
| 2 | BUSPIRONE<br>HYDROCHLORIDE TABLETS<br>USP 7.5 MG((ACTIVE<br>INGREDIENT : BUSPIRONE<br><br>HYDROCHLORIDE USP -<br>NET WT. 241.494 KGS.)) | 32199200<br>Numbers | 1 | BUSPIRONE HYDROCHLORIDE<br>USP                                   | 246.324 kg  |
|   |                                                                                                                                         |                     | 2 | LACTOSE MONOHYDRATE NF/PH<br>EUR                                 | 2358.60 kg  |
|   |                                                                                                                                         |                     | 3 | MICRO CRYSTALLINE<br>CELLULOSE NF/IP/BP/PH EUR<br>(AVICEL PH102) | 804.98 kg   |
|   |                                                                                                                                         |                     | 4 | SODIUM STARCH GLYCOLATE NF                                       | 144.90 kg   |
|   |                                                                                                                                         |                     | 5 | COLLOIDAL SILICON DIOXIDE NF                                     | 36.224 kg   |
|   |                                                                                                                                         |                     | 6 | MAGNESIUM STEARATE PH<br>EUR/NF/JP                               | 36.224 kg   |
| 3 | BUSPIRONE<br>HYDROCHLORIDE TABLETS<br>USP 10 MG((ACTIVE<br>INGREDIENT : BUSPIRONE<br><br>HYDROCHLORIDE USP -<br>NET WT. 206.956 KGS.))  | 20695600<br>Numbers | 1 | BUSPIRONE HYDROCHLORIDE<br>USP                                   | 211.095 kg  |
|   |                                                                                                                                         |                     | 2 | LACTOSE MONOHYDRATE NF/PH<br>EUR                                 | 2021.277 kg |
|   |                                                                                                                                         |                     | 3 | MICRO CRYSTALLINE<br>CELLULOSE NF/IP/BP/PH EUR<br>(AVICEL PH102) | 699.784 kg  |
|   |                                                                                                                                         |                     | 4 | SODIUM STARCH GLYCOLATE NF                                       | 124.174 kg  |
|   |                                                                                                                                         |                     | 5 | COLLOIDAL SILICON DIOXIDE NF                                     | 31.043 kg   |
|   |                                                                                                                                         |                     | 6 | MAGNESIUM STEARATE PH<br>EUR/NF/JP                               | 31.043 kg   |
| 4 | BUSPIRONE<br>HYDROCHLORIDE TABLETS<br>USP 15 MG((ACTIVE<br>INGREDIENT : BUSPIRONE                                                       | 66692200<br>Numbers | 1 | BUSPIRONE HYDROCHLORIDE<br>USP                                   | 1020.39 kg  |
|   |                                                                                                                                         |                     | 2 | LACTOSE MONOHYDRATE NF/PH                                        | 9770.040 kg |

|   |                                                                                                                                      |                     |   |                                                                  |            |
|---|--------------------------------------------------------------------------------------------------------------------------------------|---------------------|---|------------------------------------------------------------------|------------|
|   | HYDROCHLORIDE USP<br>NET WT. 1000.383 KGS.))                                                                                         |                     |   | EUR                                                              |            |
|   |                                                                                                                                      |                     | 3 | MICRO CRYSTALLINE<br>CELLULOSE NF/IP/BP/PH EUR<br>(AVICEL PH102) | 3334.61 kg |
|   |                                                                                                                                      |                     | 4 | SODIUM STARCH GLYCOLATE NF                                       | 600.230 kg |
|   |                                                                                                                                      |                     | 5 | COLLOIDAL SILICON DIOXIDE NF                                     | 150.06 kg  |
|   |                                                                                                                                      |                     | 6 | MAGNESIUM STEARATE PH<br>EUR/NF/JP                               | 150.06 kg  |
| 5 | BUSPIRONE<br>HYDROCHLORIDE TABLETS<br>USP 30 MG((ACTIVE<br>INGREDIENT : BUSPIRONE<br><br>HYDROCHLORIDE USP<br>NET WT. 655.394 KGS.)) | 21846480<br>Numbers | 1 | BUSPIRONE HYDROCHLORIDE<br>USP                                   | 668.50 kg  |
|   |                                                                                                                                      |                     | 2 | LACTOSE MONOHYDRATE NF/PH<br>EUR                                 | 6401.02 kg |
|   |                                                                                                                                      |                     | 3 | MICRO CRYSTALLINE<br>CELLULOSE NF/IP/BP/PH EUR<br>(AVICEL PH102) | 2184.65 kg |
|   |                                                                                                                                      |                     | 4 | SODIUM STARCH GLYCOLATE NF                                       | 393.24 kg  |
|   |                                                                                                                                      |                     | 5 | COLLOIDAL SILICON DIOXIDE NF                                     | 103.552 kg |
|   |                                                                                                                                      |                     | 6 | MAGNESIUM STEARATE PH<br>EUR/NF/JP                               | 98.309 kg  |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 25 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Deferred                               |
| Party Name              | ASHISH LIFE SCIENCE PRIVATE LIMITED         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM REVIW00001514AM23                   |
| RA File Number          | 03AA04011100 AM22                           |

|                                                                                                                                                                                                                                                                                                                                                                                                                                            |                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                        | 0311003600/06/05/2021 |
| <p>Norms Committee Decision:</p> <p>The Committee considered the request of firm for fixation of adhoc norms and it was decided to call for following information/documents from the firm:</p> <p><b>i. DML for each export product with Approved Composition.</b><br/> <b>ii. Master Batch Formula for each export product showing net content of inputs in export item.</b><br/> <b>iii. Wastage claimed in each export product.</b></p> |                       |

|                                                                      |                                             |
|----------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                             | 26 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                          | Case Deferred                               |
| Party Name                                                           | SHIVAM ADDITIVES PRIVATE LIMITED            |
| Meeting Number and Date                                              | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                       | HQRNORM REVIW00001551AM23                   |
| RA File Number                                                       | 13AA04002353 AM22                           |
| Licence No and Date                                                  | 1311000341/19/05/2021                       |
| <p>Norms Committee Decision:</p> <p>Deferred for comments of TE.</p> |                                             |

|                                                                                                                                                                                                                                                                                                                  |                                             |                |                    |         |              |      |                             |      |   |                 |         |   |                    |         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------|--------------------|---------|--------------|------|-----------------------------|------|---|-----------------|---------|---|--------------------|---------|
| Case No.                                                                                                                                                                                                                                                                                                         | 27 / NC/3/MEET/Dec/202223/15                |                |                    |         |              |      |                             |      |   |                 |         |   |                    |         |
| Case Status                                                                                                                                                                                                                                                                                                      | Case Approved                               |                |                    |         |              |      |                             |      |   |                 |         |   |                    |         |
| Party Name                                                                                                                                                                                                                                                                                                       | KALKI HEALTHCARE PRIVATE LIMITED            |                |                    |         |              |      |                             |      |   |                 |         |   |                    |         |
| Meeting Number and Date                                                                                                                                                                                                                                                                                          | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |                    |         |              |      |                             |      |   |                 |         |   |                    |         |
| HQ File Number                                                                                                                                                                                                                                                                                                   | HQRNORM REVIW00001509AM23                   |                |                    |         |              |      |                             |      |   |                 |         |   |                    |         |
| RA File Number                                                                                                                                                                                                                                                                                                   | 34AA04002336 AM22                           |                |                    |         |              |      |                             |      |   |                 |         |   |                    |         |
| Licence No and Date                                                                                                                                                                                                                                                                                              | 3411000712/09/06/2021                       |                |                    |         |              |      |                             |      |   |                 |         |   |                    |         |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                        |                                             |                |                    |         |              |      |                             |      |   |                 |         |   |                    |         |
| The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:                                                                                         |                                             |                |                    |         |              |      |                             |      |   |                 |         |   |                    |         |
| <table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td rowspan="2">S-(+)-2-Aminobutyramide HCL</td><td rowspan="2">1 kg</td><td>1</td><td>Propionaldehyde</td><td>1.66 kg</td></tr><tr><td>2</td><td>Acetone Cynohydrin</td><td>2.43 kg</td></tr></table> |                                             | Export Product | Qty.               | Sl. No. | Import Items | Qty. | S-(+)-2-Aminobutyramide HCL | 1 kg | 1 | Propionaldehyde | 1.66 kg | 2 | Acetone Cynohydrin | 2.43 kg |
| Export Product                                                                                                                                                                                                                                                                                                   | Qty.                                        | Sl. No.        | Import Items       | Qty.    |              |      |                             |      |   |                 |         |   |                    |         |
| S-(+)-2-Aminobutyramide HCL                                                                                                                                                                                                                                                                                      | 1 kg                                        | 1              | Propionaldehyde    | 1.66 kg |              |      |                             |      |   |                 |         |   |                    |         |
|                                                                                                                                                                                                                                                                                                                  |                                             | 2              | Acetone Cynohydrin | 2.43 kg |              |      |                             |      |   |                 |         |   |                    |         |

|  |  |   |              |         |
|--|--|---|--------------|---------|
|  |  | 3 | Tararic Acid | 1.10 kg |
|--|--|---|--------------|---------|

RA concerned may take further necessary action as per above decision of NC.

|                         |                                                       |
|-------------------------|-------------------------------------------------------|
| Case No.                | 28 / NC/3/MEET/Dec/202223/15                          |
| Case Status             | Case Deferred                                         |
| Party Name              | VARTIKA CHEMICALS AND PHARMACEUTICALS PRIVATE LIMITED |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022           |
| HQ File Number          | HQRNORM APPLY 00002099AM23                            |
| RA File Number          | NA                                                    |
| Licence No and Date     | 1311000462/22/07/2021                                 |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:

- i. Copy of DML with Approved Composition of Export Product.**

**Complete technical details as per Annexure to Appendix 4E.**

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 29 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Deferred                               |
| Party Name              | AMI ORGANICS LIMITED                        |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001128AM23                  |
| RA File Number          | 52AX04000054 AM23                           |
| Licence No and Date     | 5211002565/01/06/2022                       |

**Norms Committee Decision:**

Deferred for comments of TE.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 30 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | MAIVA PHARMA PRIVATE LIMITED                |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001143AM23                  |
| RA File Number          | 07AX04000272 AM23                           |
| Licence No and Date     | 0711004133/01/06/2022                       |

## Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jan/202122/13 dated 21/01/2022** against advance authorization No. **0711001669 dated 09.08.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                      | Qty.          | Sl. No. | Import items                                                                                | Qty.                           |
|---------|-----------------------------------------------------|---------------|---------|---------------------------------------------------------------------------------------------|--------------------------------|
| 1       | Bumetanide Injection 0.25mg/mL, 4mL vial            | 90909 Number  | 1       | V-35 4031/45G DC SIL<br>WesterSELECT RS P02(13mm Serum<br>Non laminated Bromobutyl R/S RFS) | Relevant as per packing policy |
| 2       | Bumetanide Injection 0.25mg/mL, 10mL vial           | 145454 Number | 2       | V-35 4031/45G DC SIL<br>WesterSELECT RS P02(13mm Serum<br>Non laminated Bromobutyl R/S RFS) | Relevant as per packing policy |
| 3       | Famotidine Injection 10mg/mL, 2mL vial              | 127272 Number | 3       | V-35 4031/45G DC SIL<br>WesterSELECT RS P02(13mm Serum<br>Non laminated Bromobutyl R/S RFS) | Relevant as per packing policy |
| 4       | Diltiazem Hydrochloride Injection 5mg/mL, 5mL vial  | 90909 Number  | 4       | V-35 4031/45G DC SIL<br>WesterSELECT RS P02(13mm Serum<br>Non laminated Bromobutyl R/S RFS) | Relevant as per packing policy |
| 5       | Diltiazem Hydrochloride Injection 5mg/mL, 25mL vial | 47619 Number  | 5       | V-35 4031/45G DC SIL<br>WesterSELECT RS P02(13mm Serum<br>Non laminated Bromobutyl R/S RFS) | Relevant as per packing policy |

RA concerned may take further necessary action as per above decision of NC.

|                           |                                             |
|---------------------------|---------------------------------------------|
| Case No.                  | 31 / NC/3/MEET/Dec/202223/15                |
| Case Status               | Case Deferred                               |
| Party Name                | YASHO INDUSTRIES LIMITED                    |
| Meeting Number and Date   | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number            | HQRNORM APPLY 00001144AM23                  |
| RA File Number            | 03AX04000995 AM23                           |
| Licence No and Date       | 0311015188/02/06/2022                       |
| Norms Committee Decision: |                                             |

Deferred for comments of TE.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 32 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | AARTI DRUGS LIMITED                         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001150AM23                  |
| RA File Number          | 03AX04000872 AM23                           |
| Licence No and Date     | 0311015199/02/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0311013055 dated 17/03/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                  | Qty. | Sl. No. | Import items                                                     | Qty.     |
|---------------------------------|------|---------|------------------------------------------------------------------|----------|
| Ciprofloxacin Hydrochloride USP | 1 kg | 1       | Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate | 1.240 kg |
|                                 |      | 2       | Piperazine Anhydrous                                             | 0.390 kg |

RA concerned may take further necessary action as per above decision of NC

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 33 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | GLAND PHARMA LIMITED                        |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001158AM23                  |
| RA File Number          | 09AX04000093 AM23                           |
| Licence No and Date     | 0911003095/02/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/14 dated 07/12/2022** against advance authorization No.

**0911002409 dated 28/01/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                                                                                                                                                                                                                                                                                                            | Qty.     | Sl. No. | Import items       | Qty.           |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|--------------------|----------------|
| 1       | Nadroparin Calcium Injection (Low Molecular Weight Heparin) 2850 IU/0.3ml PFS (IU Condition: The firm should account for 7.125 Kgs of input at SL No. 1 and 3,00,000 Nos each of input at SL No. 2,3,4,5 of the import list in the resultant product should be reflected in SBs. Export to : Kazakhstan Buyer Name & Address as per DML ) | 1 Number | 1       | Nadroparin Calcium | 26.125 mg      |
|         |                                                                                                                                                                                                                                                                                                                                           |          | 2       | Barrel Syringes    | 1.05 Numbers   |
|         |                                                                                                                                                                                                                                                                                                                                           |          | 3       | Plunger Stoppers   | 1.1085 Numbers |
|         |                                                                                                                                                                                                                                                                                                                                           |          | 4       | Plunger Rods       | 1.0165 Numbers |
|         |                                                                                                                                                                                                                                                                                                                                           |          | 5       | Preventis          | 1.05 Numbers   |
| 2       | Nadroparin Calcium Injection (Low Molecular Weight Heparin) 5700 IU/0.6ml PFS(IU Condition: The firm should account for 18.857 Kgs of input at SL No. 6 and 3,97,000 Nos each of input at SL No. 7,8,9,10 of the import list in the resultant product should be reflected in SBs. Export to : Kazakhstan Buyer Name & Address as per DML) | 1 Number | 1       | Nadroparin Calcium | 52.25 mg       |
|         |                                                                                                                                                                                                                                                                                                                                           |          | 2       | Barrel Syringes    | 1.05 Numbers   |
|         |                                                                                                                                                                                                                                                                                                                                           |          | 3       | Plunger Stoppers   | 1.1085 Numbers |
|         |                                                                                                                                                                                                                                                                                                                                           |          | 4       | Plunger Rods       | 1.0165 Numbers |
|         |                                                                                                                                                                                                                                                                                                                                           |          | 5       | Preventis          | 1.05 Numbers   |

RA concerned may take further necessary action as per above decision of NC.

|                           |                                             |
|---------------------------|---------------------------------------------|
| Case No.                  | 34 / NC/3/MEET/Dec/202223/15                |
| Case Status               | Case Approved                               |
| Party Name                | STERILE INDIA PRIVATE LIMITED               |
| Meeting Number and Date   | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number            | HQRNORM APPLY 00001161AM23                  |
| RA File Number            | 05AX04000552 AM23                           |
| Licence No and Date       | 0511012969/02/06/2022                       |
| Norms Committee Decision: |                                             |

The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                          | Qty. | Sl. No. | Import items                       | Qty.      |
|---------------------------------------------------------|------|---------|------------------------------------|-----------|
| Meropenem Sodium Sterile<br>((Meropenem for Injection)) | 1 kg | 1       | Meropenem Trihydrate (Non Sterile) | 0.8968 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 35 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | SUN PHARMACEUTICAL INDUSTRIES LIMITED       |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001163AM23                  |
| RA File Number          | 05AX04000658 AM23                           |
| Licence No and Date     | 0511012970/02/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **7/82-ALC4/2020 dated 04.12.2020** against advance authorization No. **0510414952 dated 20.08.2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export Product                                   | Qty.    | Sl. No. | Import items   | Qty.       |
|---------|--------------------------------------------------|---------|---------|----------------|------------|
| 1       | Clarithromycin Carbomer Granules<br>27.5% / 28%  | 1500 kg | 1       | Carbopol 974 P | 300 kg     |
|         |                                                  |         | 2       | Clarithromycin | 416.55 kg  |
| 2       | Clarithromycin Carbomer Granules<br>43.75% / 44% | 1340 kg | 1       | Carbopol 974 P | 495.8 kg   |
|         |                                                  |         | 2       | Clarithromycin | 588.796 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 36 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | SENTISS PHARMA PRIVATE LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001164AM23                  |
| RA File Number          | 05AX04000638 AM23                           |
| Licence No and Date     | 0511012971/02/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jan/202021/4 dated 12.02.2021** against advance authorization No. **0510413989 dated 13.04.2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export Product                                    | Qty    | Sl. No. | Import Items                           | Qty     |
|---------------------------------------------------|--------|---------|----------------------------------------|---------|
| Kombinil-DUO Eye/Ear Drops 5ml Vial (5 mg / Vial) | 1 Pack | 1       | Dexamethasone Micronised PH EUR USP JP | 5.10 mg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 37 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Deferred                               |
| Party Name              | OC SPECIALITIES PRIVATE LIMITED             |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001173AM23                  |
| RA File Number          | 03AX04001017 AM23                           |
| Licence No and Date     | 0311015227/03/06/2022                       |

**Norms Committee Decision:**

Deferred for comments of TE.

|             |                               |
|-------------|-------------------------------|
| Case No.    | 38 / NC/3/MEET/Dec/202223/15  |
| Case Status | Case Approved                 |
| Party Name  | CONNEX PHARMA PRIVATE LIMITED |

| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |                      |          |              |     |                                        |      |   |                      |          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------|----------------------|----------|--------------|-----|----------------------------------------|------|---|----------------------|----------|
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | HQRNORM APPLY 00001182AM23                  |                |                      |          |              |     |                                        |      |   |                      |          |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 26AX04000017 AM23                           |                |                      |          |              |     |                                        |      |   |                      |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 2611000608/03/06/2022                       |                |                      |          |              |     |                                        |      |   |                      |          |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Apr/202223/1 dated 29/04/2022</b> against advance authorization No. <b>2611000203 dated 26-07-2021</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty</th> </tr> </thead> <tbody> <tr> <td>CHLOROMETHYL ISOPROPYL CARBONATE (API)</td> <td>1 kg</td> <td>1</td> <td>METHYLCHLORO FORMATE</td> <td>0.943 kg</td> </tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision of NC.</p> |                                             | Export Product | Qty                  | Sl. No.  | Import Items | Qty | CHLOROMETHYL ISOPROPYL CARBONATE (API) | 1 kg | 1 | METHYLCHLORO FORMATE | 0.943 kg |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Qty                                         | Sl. No.        | Import Items         | Qty      |              |     |                                        |      |   |                      |          |
| CHLOROMETHYL ISOPROPYL CARBONATE (API)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 1 kg                                        | 1              | METHYLCHLORO FORMATE | 0.943 kg |              |     |                                        |      |   |                      |          |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                          | 39 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                       | Case Deferred                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                        | AETHER INDUSTRIES LIMITED                   |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                           | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                    | HQRNORM APPLY 00001183AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                    | 52AX04000220 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                               | 5211002594/03/06/2022                       |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:</p> <p>i. <b>Complete chemistry, molecular weight, percentage yield on molar basis etc. as per Annexure to Appendix 4E.</b><br/> ii. <b>Indigenous item, if any.</b><br/> iii. <b>Production / Consumption data duly certified by CA.</b></p> |                                             |

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|-------------|---------------------------------|
| Case No.    | 40 / NC/3/MEET/Dec/202223/15    |
| Case Status | Case Deferred                   |
| Party Name  | OC SPECIALITIES PRIVATE LIMITED |

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| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001188AM23                  |
| RA File Number               | 03AX04001018 AM23                           |
| Licence No and Date          | 0311015240/03/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                     | 41 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | MITHILA RASAYAN PRIVATE LIMITED             |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001167AM23                  |
| RA File Number               | 03AX04001036 AM23                           |
| Licence No and Date          | 0311015222/03/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                     | 42 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                  | Case Approved                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                   | SANOFI INDIA LIMITED                        |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                               | HQRNORM APPLY 00001172AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                               | 03AX04000912 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                          | 0311015226/03/06/2022                       |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                    |                                             |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Mar/202122/15 dated 17/03/2022</b> against advance authorization No. <b>0311002322 dated 10-03-2021</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |
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|---|--------------------------------------------------------------------------------------------------------------------|-----------------|---|------------|-----------|
|   | 192mg/Tablet))                                                                                                     |                 |   |            |           |
| 2 | Festal N Dragees (Tablets) 2x10s((Total net Weight, Pancreatin 5312.5 Kgs Strength of Pancreatin 212.50mg/Tablet)) | 1 Number Tablet | 2 | PANCREATIN | 216.75 mg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 43 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | HONOUR LAB LIMITED                          |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001225AM23                  |
| RA File Number          | 09AX04000202 AM23                           |
| Licence No and Date     | 0911003130/06/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0911002884 dated 21/04/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                           | Qty. | Sl. No. | Import items                        | Qty.     |
|------------------------------------------------------------------------------------------|------|---------|-------------------------------------|----------|
| 1-(2,2-DIMETHOXYETHYL)-5-METHOXY-6-(METHOXYCARBONYL)-4-OXO-1H-PYRIDINE-3-CARBOXYLIC ACID | 1 kg | 1       | Amino Acetyldehyde Di Methyl Acetal | 0.575 kg |
|                                                                                          |      | 2       | Methyl-4-Methoxy Acetoacetate       | 0.725 kg |
|                                                                                          |      | 3       | Di Methyl Oxalate                   | 1.17 kg  |
|                                                                                          |      | 4       | Lithium Hydroxide                   | 0.300 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 44 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | AARTI DRUGS LIMITED                         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001232AM23                  |
| RA File Number          | 03AX04001034 AM23                           |
| Licence No and Date     | 0311015299/07/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0311013055 dated 17/03/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product    | Qty. | Sl. No. | Import items                                                     | Qty.     |
|-------------------|------|---------|------------------------------------------------------------------|----------|
| Ciprofloxacin HCL | 1 kg | 1       | Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate | 1.240 kg |
|                   |      | 2       | Piperazine Anhydrous                                             | 0.390 kg |

RA concerned may take further necessary action as per above decision of NC.

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|-------------------------|---------------------------------------------|
| Case No.                | 45 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | GLENMARK PHARMACEUTICALS LIMITED            |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001234AM23                  |
| RA File Number          | 03AX04001026 AM23                           |
| Licence No and Date     | 0311015302/07/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Oct/202223/11 dated 31/10/2022** against advance authorization No. **0311004402 dated 07/06/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export Product                                                                                                                                                                                              | Qty.          | Sl. No. | Import items             | Qty.     |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------|--------------------------|----------|
| 1       | OFLOMIL LAK NAIL 5 Percent (Pack size 2.5ml) (OfloMil Lacquer/Amorolfine Hydrochloride Nail Lacquer)((Each 1 ml contains Amorolfine hydrochloride 50 mg) (Net wt of Amorolfine Hydrochloride is 12.50 Kgs)) | 100000 Number | 1       | Amorolfine Hydrochloride | 12.75 kg |
| 2       | OFLOMIL LAK NAIL 5 Percent (Pack size 5ml) (OfloMil Lacquer/Amorolfine Hydrochloride Nail Lacquer)((Each 1 ml contains Amorolfine hydrochloride 50 mg) (Net wt of Amorolfine Hydrochloride is 25.00 Kgs))   | 100000 Number | 2       | Amorolfine Hydrochloride | 25.50 kg |

RA concerned may take further necessary action as per above decision of NC.

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|-------------------------|---------------------------------------------|
| Case No.                | 46 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | FDC LIMITED                                 |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001235AM23                  |
| RA File Number          | 03AX04000861 AM23                           |
| Licence No and Date     | 0311015303/07/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jul/202122/4 dated 15/07/2021** against advance authorization No. **0311004667 dated 16/06/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                     | Qty.        | Sl. No. | Import items           | Qty.      |
|------------------------------------------------------------------------------------|-------------|---------|------------------------|-----------|
| BRIMONIDINE EYE DROPS 5ML AND IOBRIM EYE DROPS 5ML((Each vial contains 0.010 GM of | 75000 Vials | 1       | BRIMONIDINE L TARTRATE | 765 grams |

|                                                                             |  |  |  |  |
|-----------------------------------------------------------------------------|--|--|--|--|
| Brimonidine L Tartrate Net Wt of bulk drug is 750 gms))                     |  |  |  |  |
| RA concerned may take further necessary action as per above decision of NC. |  |  |  |  |

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|------------------------------|---------------------------------------------|
| Case No.                     | 47 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | GLENMARK PHARMACEUTICALS LIMITED            |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001238AM23                  |
| RA File Number               | 03AX04000996 AM23                           |
| Licence No and Date          | 0311015308/07/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                                                                                      | 48 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                                                                                   | Case Deferred                               |
| Party Name                                                                                                                    | CIPLA LIMITED                               |
| Meeting Number and Date                                                                                                       | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                | HQRNORM APPLY 00001239AM23                  |
| RA File Number                                                                                                                | 03AX04000947 AM23                           |
| Licence No and Date                                                                                                           | 0311015309/07/06/2022                       |
| Norms Committee Decision:                                                                                                     |                                             |
| The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: |                                             |
| i. <b>DML.</b><br>ii. <b>Master Batch Formula.</b>                                                                            |                                             |

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|-------------------------|---------------------------------------------|
| Case No.                | 49 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Deferred                               |
| Party Name              | ENCUBE ETHICALS PRIVATE LIMITED             |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001229AM23                  |
| RA File Number          | 03AX04000530 AM23                           |

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| Licence No and Date                                                                                                                                                                                           | 0311015288/07/06/2022 |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and it was decided to call the firm for attending <b>Personal Hearing</b> before Norms Committee to explain its case.</p> |                       |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                    | 50 / NC/3/MEET/Dec/202223/15                |         |                                                                         |          |                |     |         |                   |      |                      |      |   |                                                                         |          |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                 | Case Approved                               |         |                                                                         |          |                |     |         |                   |      |                      |      |   |                                                                         |          |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                  | DIAMINES AND CHEMICALS LIMITED              |         |                                                                         |          |                |     |         |                   |      |                      |      |   |                                                                         |          |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                     | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |         |                                                                         |          |                |     |         |                   |      |                      |      |   |                                                                         |          |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                              | HQRNORM APPLY 00001243AM23                  |         |                                                                         |          |                |     |         |                   |      |                      |      |   |                                                                         |          |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                              | 34AX04000188 AM23                           |         |                                                                         |          |                |     |         |                   |      |                      |      |   |                                                                         |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                         | 3411002347/07/06/2022                       |         |                                                                         |          |                |     |         |                   |      |                      |      |   |                                                                         |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                   |                                             |         |                                                                         |          |                |     |         |                   |      |                      |      |   |                                                                         |          |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Sep/202223/9 dated 07/10/2022</b> against advance authorization No. <b>3411000643 dated 27/05/2021</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |         |                                                                         |          |                |     |         |                   |      |                      |      |   |                                                                         |          |
| <table><tr><td>Export Product</td><td>Qty</td><td>Sl. No.</td><td>Import Item Name.</td><td>Qty.</td></tr><tr><td>PIPERAZINE ANHYDROUS</td><td>1 kg</td><td>1</td><td>PIPERAZINE CRUDE OR PIPERAZINE MIXTURE<br/>(Percentage purity NMT 48.1%)</td><td>2.047 kg</td></tr></table>                                                                                                                           |                                             |         |                                                                         |          | Export Product | Qty | Sl. No. | Import Item Name. | Qty. | PIPERAZINE ANHYDROUS | 1 kg | 1 | PIPERAZINE CRUDE OR PIPERAZINE MIXTURE<br>(Percentage purity NMT 48.1%) | 2.047 kg |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                              | Qty                                         | Sl. No. | Import Item Name.                                                       | Qty.     |                |     |         |                   |      |                      |      |   |                                                                         |          |
| PIPERAZINE ANHYDROUS                                                                                                                                                                                                                                                                                                                                                                                        | 1 kg                                        | 1       | PIPERAZINE CRUDE OR PIPERAZINE MIXTURE<br>(Percentage purity NMT 48.1%) | 2.047 kg |                |     |         |                   |      |                      |      |   |                                                                         |          |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                 |                                             |         |                                                                         |          |                |     |         |                   |      |                      |      |   |                                                                         |          |

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|---------------------------|---------------------------------------------|
| Case No.                  | 51 / NC/3/MEET/Dec/202223/15                |
| Case Status               | Case Approved                               |
| Party Name                | FINE ORGANIC INDUSTRIES LIMITED             |
| Meeting Number and Date   | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number            | HQRNORM APPLY 00001230AM23                  |
| RA File Number            | 03AX04000940 AM23                           |
| Licence No and Date       | 0311015296/07/06/2022                       |
| Norms Committee Decision: |                                             |

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **10/82-ALC4/2018 dated 16.10.2018** against advance authorization No. **0310821155 dated 22.05.2018**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product    | Qty. | Sl. No. | Import items  | Qty.     |
|-------------------|------|---------|---------------|----------|
| STEARYL ERUCAMIDE | 1 kg | 1       | ERUCIC ACID   | 0.592 kg |
|                   |      | 2       | STEARYL AMINE | 0.471 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 52 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | RUBICON RESEARCH PRIVATE LIMITED            |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001250AM23                  |
| RA File Number          | 03AX04000906 AM23                           |
| Licence No and Date     | 0311015328/07/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0311014526 dated 06/05/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                                                                                                                                                      | Qty.     | Sl. No. | Import items             | Qty.               |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|--------------------------|--------------------|
| 1       | Maxigesic cold & flu Hot Drink 500mg/150mg Sachets (Paracetamol & Ibuprofen Sachets 500 mg & 150 mg)(No. of Sachets 350,000 (Net content of Ibuprofen Lysine Salt IH API 89.78 kg)) | 1 Number | 1       | Ibuprofen Lysine Salt IH | 258.88 mg / Sachet |
| 2       | Maxigesic cold & flu Hot Drink                                                                                                                                                      | 1 Number | 2       | Ibuprofen Lysine Salt    | 517.77 mg /        |

|  |                                                                                                                                                         |  |  |    |        |
|--|---------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|----|--------|
|  | 1000mg/300mg Sachets (Paracetamol & Ibuprofen Sachets 1000 mg & 300 mg)(No. of Sachets 350,000 (Net content of Ibuprofen Lysine Salt IH API 179.55 kg)) |  |  | IH | Sachet |
|--|---------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|----|--------|

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 53 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | GLENMARK PHARMACEUTICALS LIMITED            |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001231AM23                  |
| RA File Number          | 03AX04001050 AM23                           |
| Licence No and Date     | 0311015297/07/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202122/9 dated 15/10/2021** against advance authorization No. **0310837175 dated 14/07/2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export Product                                                                                                                | Qty.         | Import items                           | Qty.      |
|---------|-------------------------------------------------------------------------------------------------------------------------------|--------------|----------------------------------------|-----------|
| 1       | Clobetasol Propionate Foam 0.05percent 50gm((Net. wt. of Clobetasol Propionate USP (Micronized) is 5.00 Kgs)                  | 200000 Packs | CLOBETASOL PROPIONATE USP (MICRONIZED) | 36.295 kg |
| 2       | Clobetasol Propionate Foam 0.05percent 100gm((Net. wt. of Clobetasol Propionate USP (Micronized) is 10.00 Kgs.))              | 200000 Packs |                                        |           |
| 3       | Clobetasol Propionate Cream USP 0.05percent (Pack Size 15gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.15 Kgs)) | 200000 Packs |                                        |           |
| 4       | Clobetasol Propionate Cream USP 0.05percent (Pack size 30gm)((Net Weight of Clobetasol                                        | 200000 Packs |                                        |           |

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|    | Propionate USP (Micronized) 0.300 Kgs))                                                                                           |             |  |  |
| 5  | Clobetasol Propionate Cream USP 0.05percent (Pack size 45 gm)(( Net Weight of Clobetasol Propionate USP (Micronized) 1.125 Kgs))  | 50000 Packs |  |  |
| 6  | Clobetasol Propionate Cream USP 0.05percent (Pack size 60gm)((Net Weight of Clobetasol Propionate USP (Micronized) 1.500 Kgs))    | 50000 Packs |  |  |
| 7  | Clobetasol Propionate Ointment USP 0.05percent (Pack size 15gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.375 Kgs)) | 50000 Packs |  |  |
| 8  | Clobetasol Propionate Ointment USP 0.05percent (Pack size 30gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.750 Kgs)) | 50000 Packs |  |  |
| 9  | Clobetasol Propionate Ointment USP 0.05percent (Pack size 45gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.900 Kgs)) | 40000 Packs |  |  |
| 10 | Clobetasol Propionate Ointment USP 0.05percent (Pack size 60gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.600 Kgs)) | 20000 Packs |  |  |
| 11 | Clobetasol Propionate Spray 0.05percent (Pack size 59ml)((Net Weight of Clobetasol Propionate USP (Micronized) 1.180 Kgs))        | 40000 Packs |  |  |
| 12 | Clobetasol Propionate Spray 0.05percent (Pack size 125ml)((Net Weight of Clobetasol Propionate USP (Micronized) 2.500 Kgs))       | 40000 Packs |  |  |
| 13 | Clobetasol Prop. Top Sol USP, 0.05percent 25ml((Net Weight of Clobetasol Propionate USP (Micronized) 0.625 Kgs))                  | 50000 Packs |  |  |
| 14 | Clobetasol Prop. Top Sol USP, 0.05percent 50ml((Net Weight of Clobetasol Propionate USP (Micronized) 1.50 Kgs))                   | 60000 Packs |  |  |
| 15 | Clobetasol Pro Shampoo, 0.05 percent 118ml((Net                                                                                   | 60000       |  |  |

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|    | Weight of Clobetasol Propionate USP (Micronized) Packs<br>3.54 Kgs))                                                                          |                |  |  |
| 16 | Clobetasol Propionate Foam 0.05percent 100gm<br>(Emulsion Formulation)(( Net. wt. of Clobetasol<br>Propionate USP (Micronized) is 2.50 Kgs.)) | 50000<br>Packs |  |  |
| 17 | Clobetasol Propionate Foam 0.05percent 50gm<br>(Emulsion Formulation)(( Net. wt. of Clobetasol<br>Propionate USP (Micronized) is 1.250 Kgs.)) | 50000<br>Packs |  |  |

RA concerned may take further necessary action as per above decision of NC.

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--|--|--|
| Case No.                                                                                                                                                                                        | 54 / NC/3/MEET/Dec/202223/15                |  |  |  |
| Case Status                                                                                                                                                                                     | Case Approved                               |  |  |  |
| Party Name                                                                                                                                                                                      | WEXFORD LABORATORIES PRIVATE LIMITED        |  |  |  |
| Meeting Number and Date                                                                                                                                                                         | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |  |  |  |
| HQ File Number                                                                                                                                                                                  | HQRNORM APPLY 00001257AM23                  |  |  |  |
| RA File Number                                                                                                                                                                                  | 07AX04000289 AM23                           |  |  |  |
| Licence No and Date                                                                                                                                                                             | 0711004250/08/06/2022                       |  |  |  |
| Norms Committee Decision:                                                                                                                                                                       |                                             |  |  |  |
| The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |  |  |  |
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| Case No.       | 55 / NC/3/MEET/Dec/202223/15                |  |  |  |
| Case Status    | Case Deferred                               |  |  |  |
| Party Name     | EAST AFRICAN INDIA OVERSEAS                 |  |  |  |
| Meeting Number | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |  |  |  |

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|------------------------------|----------------------------|
| and Date                     |                            |
| HQ File Number               | HQRNORM APPLY 00001260AM23 |
| RA File Number               | 05AX04000587 AM23          |
| Licence No and Date          | 0511013087/08/06/2022      |
| Norms Committee Decision:    |                            |
| Deferred for comments of TE. |                            |

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|------------------------------|---------------------------------------------|
| Case No.                     | 56 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | YASHO INDUSTRIES LIMITED                    |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001266AM23                  |
| RA File Number               | 03AX04001106 AM23                           |
| Licence No and Date          | 0311015346/08/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 57 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | AUORE LIFE SCIENCES PRIVATE LIMITED         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001271AM23                  |
| RA File Number               | 09AX04000171 AM23                           |
| Licence No and Date          | 0911003148/08/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                                                                                                       | 58 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                                                                    | Case Approved                               |
| Party Name                                                                                                     | NATCO PHARMA LIMITED                        |
| Meeting Number and Date                                                                                        | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                 | HQRNORM APPLY 00001280AM23                  |
| RA File Number                                                                                                 | 09AX04000174 AM23                           |
| Licence No and Date                                                                                            | 0911003150/08/06/2022                       |
| Norms Committee Decision:                                                                                      |                                             |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / |                                             |

import item in Meeting No. **NC/3/MEET/Feb/202122/14 dated 21/02/2022** against advance authorization No. **0911000714 dated 23-04-2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                                                                                                       | Qty.     | Sl. No. | Import items                                 | Qty.     |
|---------|--------------------------------------------------------------------------------------------------------------------------------------|----------|---------|----------------------------------------------|----------|
| 1       | NITROGLYCERIN<br>SUBLINGUAL TABLETS USP<br>0.3 mg-Each Tablet contains<br>Nitroglycerin USP 0.3 mg (1 x<br>1,80,000 = 1,80,000 Tabs) | 1 Number | 1       | DILUTED NITROGLYCERIN<br>USP 1.95 %          | 15.70 mg |
|         |                                                                                                                                      |          | 2       | Glyceryl Monosterate (Imwitor 491<br>powder) | 1.60 mg  |
| 2       | NITROGLYCERIN<br>SUBLINGUAL TABLETS USP<br>0.4 mg-Each Tablet contains<br>Nitroglycerin USP 0.4 mg (3<br>x12,00,000= 36,00,000 Tabs) | 1 Number | 1       | DILUTED NITROGLYCERIN<br>USP 1.95 %          | 20.93 mg |
|         |                                                                                                                                      |          | 2       | Glyceryl Monosterate (Imwitor 491<br>powder) | 1.60 mg  |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 59 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | UPL LIMITED                                 |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001254AM23                  |
| RA File Number          | 03AX04000946 AM23                           |
| Licence No and Date     | 0311015330/08/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **6/82-ALC4/2020 dated 13.11.2020** against advance authorization No. **0310831562 dated 16.09.2019**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product | Qty. | Sl. No. | Import items | Qty. |
|----------------|------|---------|--------------|------|
|----------------|------|---------|--------------|------|

|                     |      |   |                   |          |
|---------------------|------|---|-------------------|----------|
| Triphenyl Phosphite | 1 kg | 1 | Phenol            | 0.937 kg |
|                     |      | 2 | Yellow Phosphorus | 0.1 kg   |

RA concerned may take further necessary action as per above decision of NC.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 60 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | NASENSE LABS PRIVATE LIMITED                |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001297AM23                  |
| RA File Number               | 09AX04000213 AM23                           |
| Licence No and Date          | 0911003160/09/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

| Case No.                                                                                                                                                                                                                                                                                                                                                                                                    | 61 / NC/3/MEET/Dec/202223/15                |                |                                                                    |         |              |      |                          |      |   |                                                                    |         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------|--------------------------------------------------------------------|---------|--------------|------|--------------------------|------|---|--------------------------------------------------------------------|---------|
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                 | Case Approved                               |                |                                                                    |         |              |      |                          |      |   |                                                                    |         |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                  | GODAVARI DRUGS LIMITED                      |                |                                                                    |         |              |      |                          |      |   |                                                                    |         |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                     | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |                                                                    |         |              |      |                          |      |   |                                                                    |         |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                              | HQRNORM APPLY 00001293AM23                  |                |                                                                    |         |              |      |                          |      |   |                                                                    |         |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                              | 09AX04000117 AM23                           |                |                                                                    |         |              |      |                          |      |   |                                                                    |         |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                         | 0911003154/09/06/2022                       |                |                                                                    |         |              |      |                          |      |   |                                                                    |         |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                   |                                             |                |                                                                    |         |              |      |                          |      |   |                                                                    |         |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Jun/202223/5 dated 08/07/2022</b> against advance authorization No. <b>0911002342 dated 20/01/2022</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |                |                                                                    |         |              |      |                          |      |   |                                                                    |         |
| <table><tr><th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr><tr><td>CIPROFLOXACIN HCL / BASE</td><td>1 kg</td><td>1</td><td>ETHYL 3-CYCLOPROPYLAMINO-2-(2,4-DICHLORO-5-FLUOROBENZOYL) ACRYLATE</td><td>1.24 kg</td></tr></table>                                                                                                                                  |                                             | Export product | Qty.                                                               | Sl. No. | Import items | Qty. | CIPROFLOXACIN HCL / BASE | 1 kg | 1 | ETHYL 3-CYCLOPROPYLAMINO-2-(2,4-DICHLORO-5-FLUOROBENZOYL) ACRYLATE | 1.24 kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                              | Qty.                                        | Sl. No.        | Import items                                                       | Qty.    |              |      |                          |      |   |                                                                    |         |
| CIPROFLOXACIN HCL / BASE                                                                                                                                                                                                                                                                                                                                                                                    | 1 kg                                        | 1              | ETHYL 3-CYCLOPROPYLAMINO-2-(2,4-DICHLORO-5-FLUOROBENZOYL) ACRYLATE | 1.24 kg |              |      |                          |      |   |                                                                    |         |

|  |  |   |                      |          |
|--|--|---|----------------------|----------|
|  |  | 2 | CAUSTIC SODA FLAKES  | 0.35 kg  |
|  |  | 3 | TOLUENE              | 0.123 kg |
|  |  | 4 | ANHYDROUS PIPERAZINE | 0.39 kg  |
|  |  | 5 | METHANOL             | 1.00 kg  |

RA concerned may take further necessary action as per above decision of NC.

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| Case No.                | 62 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | GLAND PHARMA LIMITED                        |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001295AM23                  |
| RA File Number          | 26AX04000021 AM23                           |
| Licence No and Date     | 2611000614/09/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/7 dated 16/09/2022** against advance authorization No. **0910067519 dated 14/05/2019**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export Product                                                                                    | Qty      | Sl. No. | Import Items                      | Qty                  |
|---------|---------------------------------------------------------------------------------------------------|----------|---------|-----------------------------------|----------------------|
| 1       | Low molecular weight Heparin Enoxaparin Sodium Injection USP, 40mg in 0.4ml Pre-filled Syringe(-) | 1 Number | 1       | Heparin Sodium                    | 79.466 mg            |
|         |                                                                                                   |          | 2       | Barrel Syringes                   | Net + 5% wastage     |
|         |                                                                                                   |          | 3       | Plunger Stoppers                  | Net + 11.55% wastage |
|         |                                                                                                   |          | 4       | Plunger Rods                      | Net + 2.5% wastage   |
|         |                                                                                                   |          | 5       | Preventis Needle Shielding System | Net + 3% wastage     |

|   |                                                                                                   |          |   |                                   |                      |
|---|---------------------------------------------------------------------------------------------------|----------|---|-----------------------------------|----------------------|
| 2 | Low molecular weight Heparin Enoxaparin Sodium Injection USP, 60mg in 0.6ml Pre-filled Syringe(-) | 1 Number | 1 | Heparin Sodium                    | 119.187 mg           |
|   |                                                                                                   |          | 2 | Barrel Syringes                   | Net + 5% wastage     |
|   |                                                                                                   |          | 3 | Plunger Stoppers                  | Net + 10.85% wastage |
|   |                                                                                                   |          | 4 | Plunger Rods                      | Net + 1.65% wastage  |
|   |                                                                                                   |          | 5 | Preventis Needle Shielding System | Net + 3% wastage     |
| 3 | Low molecular weight Heparin Enoxaparin Sodium Injection USP, 80mg in 0.8ml Pre-filled Syringe(-) | 1 Number | 1 | Heparin Sodium                    | 158.93 mg            |
|   |                                                                                                   |          | 2 | Barrel Syringes                   | Net + 4.65% wastage  |
|   |                                                                                                   |          | 3 | Plunger Stoppers                  | Net + 12% wastage    |
|   |                                                                                                   |          | 4 | Plunger Rods                      | Net + 2.5% wastage   |
|   |                                                                                                   |          | 5 | Preventis Needle Shielding System | Net + 3% wastage     |

RA concerned may take further necessary action as per above decision of NC.

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                           | 63 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                        | Case Approved                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                         | GRAMEN BOTANICALS PRIVATE LIMITED           |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                            | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                     | HQRNORM APPLY 00001296AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                     | 05AX04000728 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                | 0511013111/09/06/2022                       |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/May/202223/4 dated 17/06/2022</b> against advance authorization No. <b>0511002405 dated 04/05/2021</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                                             |

| Export product                          | Qty. | Sl. No. | Import items                                    | Qty.    |
|-----------------------------------------|------|---------|-------------------------------------------------|---------|
| BERBERINE HYDROCHLORIDE<br>(97 PERCENT) | 1 kg | 1       | BERBERIS ARISTATA EXTRACT<br>(Assay 90% +/- 1%) | 1.00 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 64 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | HONOUR LAB LIMITED                          |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001310AM23                  |
| RA File Number          | 09AX04000134 AM22                           |
| Licence No and Date     | 0911003163/10/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Mar/202122/16 dated 08/04/2022** against advance authorization No. **0911001953 dated 26-11-2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product              | Qty. | Sl. No. | Import items                        | Qty.     |
|-----------------------------|------|---------|-------------------------------------|----------|
| TILORONE<br>DIHYDROCHLORIDE | 1 kg | 1       | 2,7-DIHYDROXY FLUOREN-9-ONE         | 0.686 kg |
|                             |      | 2       | 2-DIETHYLE AMINO ETHYL CHLORIDE HCL | 1.430 kg |
|                             |      | 3       | TETRA BUTYL AMMONIUM BROMIDE        | 0.686 kg |
|                             |      | 4       | METHONOL                            | 2.36 kg  |

RA concerned may take further necessary action as per above decision of NC.

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| Case No. | 65 / NC/3/MEET/Dec/202223/15 |
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| Case Status                  | Case Deferred                               |
| Party Name                   | RUMIT LIFE CARE                             |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001312AM23                  |
| RA File Number               | 03AX04001057 AM23                           |
| Licence No and Date          | 0311015409/10/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------|-------------------------------------|----------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                     | 66 / NC/3/MEET/Dec/202223/15                |         |                                     |          |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                  | Case Approved                               |         |                                     |          |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                   | HONOUR LAB LIMITED                          |         |                                     |          |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |         |                                     |          |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                               | HQRNORM APPLY 00001321AM23                  |         |                                     |          |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                               | 09AX04000211 AM23                           |         |                                     |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                          | 0911003166/11/06/2022                       |         |                                     |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                    |                                             |         |                                     |          |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Mar/202223/12 dated 18/11/2022</b> against advance authorization No. <b>0911002884 dated 21-04-2022</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |         |                                     |          |
|                                                                                                                                                                                                                                                                                                                                                                                                              |                                             |         |                                     |          |
| Export product                                                                                                                                                                                                                                                                                                                                                                                               | Qty.                                        | Sl. No. | Import items                        | Qty.     |
| 1-(2,2-DIMETHOXYETHYL)-5-METHOXY-6-(METHOXYCARBONYL)-4-OXO-1H-PYRIDINE-3-CARBOXYLIC ACID                                                                                                                                                                                                                                                                                                                     | 1 kg                                        | 1       | Amino Acetyldehyde Di Methyl Acetal | 0.575 kg |
|                                                                                                                                                                                                                                                                                                                                                                                                              |                                             | 2       | Methyl-4-Methoxy Acetoacetate       | 0.725 kg |
|                                                                                                                                                                                                                                                                                                                                                                                                              |                                             | 3       | Di Methyl Oxalate                   | 1.17 kg  |
|                                                                                                                                                                                                                                                                                                                                                                                                              |                                             | 4       | Lithium Hydroxide                   | 0.300 kg |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                  |                                             |         |                                     |          |

|          |                              |
|----------|------------------------------|
| Case No. | 67 / NC/3/MEET/Dec/202223/15 |
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|                         |                                             |
|-------------------------|---------------------------------------------|
| Case Status             | Case Approved                               |
| Party Name              | HONOUR LAB LIMITED                          |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001322AM23                  |
| RA File Number          | 09AX04000212 AM23                           |
| Licence No and Date     | 0911003167/11/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0911002884 dated 21-04-2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                           | Qty. | Sl. No. | Import items                        | Qty.     |
|------------------------------------------------------------------------------------------|------|---------|-------------------------------------|----------|
| 1-(2,2-DIMETHOXYETHYL)-5-METHOXY-6-(METHOXYCARBONYL)-4-OXO-1H-PYRIDINE-3-CARBOXYLIC ACID | 1 kg | 1       | Amino Acetyldehyde Di Methyl Acetal | 0.575 kg |
|                                                                                          |      | 2       | Methyl-4-Methoxy Acetoacetate       | 0.725 kg |
|                                                                                          |      | 3       | Di Methyl Oxalate                   | 1.17 kg  |
|                                                                                          |      | 4       | Lithium Hydroxide                   | 0.300 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 68 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Deferred                               |
| Party Name              | MEGHMANI FINECHEM LIMITED                   |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001341AM23                  |
| RA File Number          | 34AX04000162 AM23                           |
| Licence No and Date     | 3411002378/13/06/2022                       |

**Norms Committee Decision:**

Deferred for comments of TE.

|          |                              |
|----------|------------------------------|
| Case No. | 69 / NC/3/MEET/Dec/202223/15 |
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|------------------------------|---------------------------------------------|
| Case Status                  | Case Deferred                               |
| Party Name                   | KEVA FRAGRANCES PRIVATE LIMITED             |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001355AM23                  |
| RA File Number               | 03AX04000821 AM23                           |
| Licence No and Date          | 0311015467/13/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 70 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | SATYADIVIS PHARMACEUTICALS PRIVATE LIMITED  |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001343AM23                  |
| RA File Number               | 09AX04000118 AM23                           |
| Licence No and Date          | 0911003170/13/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                                                                                                                                                                                                                                                                                                                                                                                                     |                                             |                |                |         |              |      |                   |      |   |                |         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------|----------------|---------|--------------|------|-------------------|------|---|----------------|---------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                            | 71 / NC/3/MEET/Dec/202223/15                |                |                |         |              |      |                   |      |   |                |         |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                         | Case Approved                               |                |                |         |              |      |                   |      |   |                |         |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                          | ALTA LABORATORIES LIMITED                   |                |                |         |              |      |                   |      |   |                |         |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                             | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |                |         |              |      |                   |      |   |                |         |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                      | HQRNORM APPLY 00001356AM23                  |                |                |         |              |      |                   |      |   |                |         |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                      | 03AX04001132 AM23                           |                |                |         |              |      |                   |      |   |                |         |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                 | 0311015468/13/06/2022                       |                |                |         |              |      |                   |      |   |                |         |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                           |                                             |                |                |         |              |      |                   |      |   |                |         |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>6/82-ALC4/2020 dated 13.11.2020</b> against advance authorization No. <b>0310836920 dated 29.06.2020</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |                |                |         |              |      |                   |      |   |                |         |
| <table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>SODIUM SALICYLATE</td><td>1 kg</td><td>1</td><td>SALICYLIC ACID</td><td>0.80 kg</td></tr></table>                                                                                                                                                                                     |                                             | Export product | Qty.           | Sl. No. | Import items | Qty. | SODIUM SALICYLATE | 1 kg | 1 | SALICYLIC ACID | 0.80 kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                      | Qty.                                        | Sl. No.        | Import items   | Qty.    |              |      |                   |      |   |                |         |
| SODIUM SALICYLATE                                                                                                                                                                                                                                                                                                                                                                                   | 1 kg                                        | 1              | SALICYLIC ACID | 0.80 kg |              |      |                   |      |   |                |         |

RA concerned may take further necessary action as per above decision of NC.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 72 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | HONOUR LAB LIMITED                          |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001344AM23                  |
| RA File Number               | 092404000405 AM21                           |
| Licence No and Date          | 0911003173/13/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 73 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | KAIRAV CHEMOFARBE INDUSTRIES LIMITED        |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001357AM23                  |
| RA File Number               | 03AX04001138 AM23                           |
| Licence No and Date          | 0311015469/13/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 74 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | MANKIND PHARMA LIMITED                      |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001345AM23                  |
| RA File Number               | 05AX04000761 AM23                           |
| Licence No and Date          | 0511013170/13/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------|------------------------------|
| Case No.    | 75 / NC/3/MEET/Dec/202223/15 |
| Case Status | Case Deferred                |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Party Name                   | GLENMARK LIFE SCIENCES LIMITED              |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001358AM23                  |
| RA File Number               | 03AX04001122 AM23                           |
| Licence No and Date          | 0311015470/13/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 76 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | MANKIND PHARMA LIMITED                      |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001346AM23                  |
| RA File Number               | 05AX04000760 AM23                           |
| Licence No and Date          | 0511013171/13/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                                                                                                                                                                                                                                                                                                                                                                                                     |                                             |                |                                   |          |              |      |              |      |   |                                   |          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------|-----------------------------------|----------|--------------|------|--------------|------|---|-----------------------------------|----------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                            | 77 / NC/3/MEET/Dec/202223/15                |                |                                   |          |              |      |              |      |   |                                   |          |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                         | Case Approved                               |                |                                   |          |              |      |              |      |   |                                   |          |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                          | ROYAL PHARMA                                |                |                                   |          |              |      |              |      |   |                                   |          |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                             | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |                                   |          |              |      |              |      |   |                                   |          |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                      | HQRNORM APPLY 00001359AM23                  |                |                                   |          |              |      |              |      |   |                                   |          |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                      | 03AX04001263 AM23                           |                |                                   |          |              |      |              |      |   |                                   |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                 | 0311015473/13/06/2022                       |                |                                   |          |              |      |              |      |   |                                   |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                           |                                             |                |                                   |          |              |      |              |      |   |                                   |          |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>6/82-ALC4/2020 dated 13.11.2020</b> against advance authorization No. <b>0310838908 dated 15.10.2020</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |                |                                   |          |              |      |              |      |   |                                   |          |
| <table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>BICALUTAMIDE</td><td>1 kg</td><td>1</td><td>N - [4-CYANO-3- (TRIFLUOROMETHYL)</td><td>0.709 kg</td></tr></table>                                                                                                                                                                      |                                             | Export product | Qty.                              | Sl. No.  | Import items | Qty. | BICALUTAMIDE | 1 kg | 1 | N - [4-CYANO-3- (TRIFLUOROMETHYL) | 0.709 kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                      | Qty.                                        | Sl. No.        | Import items                      | Qty.     |              |      |              |      |   |                                   |          |
| BICALUTAMIDE                                                                                                                                                                                                                                                                                                                                                                                        | 1 kg                                        | 1              | N - [4-CYANO-3- (TRIFLUOROMETHYL) | 0.709 kg |              |      |              |      |   |                                   |          |

|                                                                                                                                            |   |  |                        |         |
|--------------------------------------------------------------------------------------------------------------------------------------------|---|--|------------------------|---------|
| SULFIDE(CHEMICAL NAME:<br>N-[4-CYANO-3-(TRIFLUORO<br>METHYL)PHENYL]-3-[(4-<br>FLUOROPHENYL THIO)] -2-<br>HYDROXY-2-METHYL<br>PROPIONALIDE) |   |  | PHENYL] METHACRYLAMIDE |         |
|                                                                                                                                            | 2 |  | 4- FLUOROTHIOPHENOL    | 0.30 kg |

RA concerned may take further necessary action as per above decision of NC.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                             |
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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 78 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Case Deferred                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | AROHEMA INGREDIENTS PRIVATE LIMITED         |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | HQRNORM APPLY 00001332AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 26AX04000018 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 2611000615/13/06/2022                       |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and it was decided to call the firm for attending <b>Personal Hearing</b> before Norms Committee for explaining its case alongwith following documents / information:</p> <p>(i) <b>Catalogue of foreign supplier for import items 3 to 5.</b></p> <p>(ii) <b>Bill of entry of import with invoice of foreign supplier.</b></p> <p>(iii) <b>Production / consumption data duly certified by a GST officer.</b></p> <p>(iv) <b>Application of Export item.</b></p> |                                             |

|                                                                      |                                             |
|----------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                             | 79 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                          | Case Deferred                               |
| Party Name                                                           | JUBILANT INGREVIA LIMITED                   |
| Meeting Number and Date                                              | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                       | HQRNORM APPLY 00001347AM23                  |
| RA File Number                                                       | 05AX04000669 AM23                           |
| Licence No and Date                                                  | 0511013173/13/06/2022                       |
| <p>Norms Committee Decision:</p> <p>Deferred for comments of TE.</p> |                                             |

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| Case No.                                                                                                                        | 80 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                                                                                     | Case Deferred                               |
| Party Name                                                                                                                      | ATUL LIMITED                                |
| Meeting Number and Date                                                                                                         | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                  | HQRNORM APPLY 00001338AM23                  |
| RA File Number                                                                                                                  | 08AX04000229 AM23                           |
| Licence No and Date                                                                                                             | 0811005174/13/06/2022                       |
| Norms Committee Decision:                                                                                                       |                                             |
| The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: |                                             |
| i. <b>Complete chemistry, molecular weight, percentage yield on molar basis etc. as per Annexure to Appendix 4E.</b>            |                                             |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 81 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | GLENMARK LIFE SCIENCES LIMITED              |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001350AM23                  |
| RA File Number               | 03AX04001135 AM23                           |
| Licence No and Date          | 0311015463/13/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                                                                                                                                                              | 82 / NC/3/MEET/Dec/202223/15                |
| Case Status                                                                                                                                                           | Case Deferred                               |
| Party Name                                                                                                                                                            | ENCUBE ETHICALS PRIVATE LIMITED             |
| Meeting Number and Date                                                                                                                                               | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                        | HQRNORM APPLY 00001340AM23                  |
| RA File Number                                                                                                                                                        | 03AX04000749 AM23                           |
| Licence No and Date                                                                                                                                                   | 0311015456/13/06/2022                       |
| Norms Committee Decision:                                                                                                                                             |                                             |
| The Committee considered the case as per agenda and it was decided to call the firm for attending <b>Personal Hearing</b> before Norms Committee to explain its case. |                                             |

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| Case No. | 83 / NC/3/MEET/Dec/202223/15 |
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| Case Status             | Case Approved                               |
| Party Name              | J B CHEMICALS AND PHARMACEUTICALS LIMITED   |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001354AM23                  |
| RA File Number          | 03AX04001153 AM23                           |
| Licence No and Date     | 0311015466/13/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0311012790 dated 14/03/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                                                                                                                                                                                                                                                                                                  | Qty.        | Sl. No | Import items              | Qty.       |
|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|--------|---------------------------|------------|
| 1       | Benzylamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and(all other flavours. Each lozenge contains (i) Benzylamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride- 1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 33.333 Kgs (ii) 14.778 Kgs (iii) 28733.356 Kgs.) | 1000 Number | 1.     | Benzylamine Hydrochloride | 3.06 gram  |
|         |                                                                                                                                                                                                                                                                                                                                 |             | 2      | Cetylpyridinium Chloride  | 1.356 gram |
|         |                                                                                                                                                                                                                                                                                                                                 |             | 3      | Isomalt ST-M              | 2586 gram  |
| 2       | Benzylamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzylamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg. Net content (i) 21.333 Kgs. (ii) 18389.439 Kgs.)                                     | 1000 Number | 4      | Benzylamine Hydrochloride | 3.06 gram  |
|         |                                                                                                                                                                                                                                                                                                                                 |             | 5      | Isomalt ST-M              | 2586 gram  |
| 3       | Benzylamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free. Each lozenge contains (i) Benzylamine Hydrochloride-(3mg (ii) Isomalt ST-M - 2586mg. Net content (i) 12 Kgs. (ii) 10344 Kgs.)                                                                                                                                  | 1000 Number | 6      | Benzylamine Hydrochloride | 3.06 gram  |
|         |                                                                                                                                                                                                                                                                                                                                 |             | 7      | Isomalt ST-M              | 2586 gram  |
| 4       | Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net                                                                                                                       | 1000 Number | 8      | Cetylpyridinium Chloride  | 1.356 gram |
|         |                                                                                                                                                                                                                                                                                                                                 |             | 9      | Isomalt ST-M              | 2586 gram  |

|   |                                                                                                                                                                                                                      |                |    |                          |           |
|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----|--------------------------|-----------|
|   | content (i) 13.333 Kg (ii) 25924.878 Kg)                                                                                                                                                                             |                |    |                          |           |
| 5 | Cetylpyridinium Chloride And Benzylamine Hydrochloride Antiseptic Lozenges Sugar Free. Each lozenge contains (i) Cetylpyridinium Chloride- 1mg (ii) Isomalt ST-M - 2586mg. Net content (i) 5.22 Kg (ii) 13498.92 Kg) | 1000<br>Number | 10 | Cetylpyridinium Chloride | 1.02 gram |
|   |                                                                                                                                                                                                                      |                | 11 | Isomalt ST-M             | 2586 gram |

RA concerned may take further necessary action as per above decision of NC.

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|-------------------------|---------------------------------------------|
| Case No.                | 84 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | GRANULES INDIA LIMITED                      |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001379AM23                  |
| RA File Number          | 09AX04000215 AM23                           |
| Licence No and Date     | 0911003175/14/06/2022                       |

Norms Committee Decision:

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The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **1/82-ALC4/2018 dated 01.05.2018** against advance authorization No. **0910064911 dated 13.04.2017**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                    | Qty. | Sl. No. | Import items             | Qty.      |
|-------------------------------------------------------------------|------|---------|--------------------------|-----------|
| Compresso GEM 70(Compresso GEM 70 (Gemfibrozil Granules DC 70% )) | 1 kg | 1       | Gemfibrozil              | 0.707 kg  |
|                                                                   |      | 2       | Pregelatinised Starch    | 0.083 kg  |
|                                                                   |      | 3       | Maize Starch             | 0.1485 kg |
|                                                                   |      | 4       | Sodium Starch Glycollate | 0.030 kg  |

|  |  |   |                       |            |
|--|--|---|-----------------------|------------|
|  |  | 5 | Povidone K 30         | 0.0270 kg  |
|  |  | 6 | Sodium Lauryl Sulfate | 0.00150 kg |
|  |  | 7 | Stearic Acid          | 0.0100 kg  |

RA concerned may take further necessary action as per above decision of NC.

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|-------------------------|---------------------------------------------|
| Case No.                | 85 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | SUN PHARMACEUTICAL INDUSTRIES LIMITED       |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001367AM23                  |
| RA File Number          | 05AX04000746 AM23                           |
| Licence No and Date     | 0511013184/14/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Mar/202122/16 dated 08/04/2022** against advance authorization No. **0511005240 dated 06-10-2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                                                                                                                                                                                                                                                                                                  | Qty.          | Sl. No. | Import items                   | Qty.         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------|--------------------------------|--------------|
| Moxifloxacin HCL & Dexamethasone Sodium Phosphate Eye Drops 0.5%w/v, 0.1% w/v, 5ml (MILFLOX DM, MILFODOX, MIFLOCO DELTA)((Each ml contain Moxifloxacin Base 5mg. equi. to Moxifloxacin HCL 5.45mg. & Dexamethasone Phosphate 1mg equi. to Dexamethasone Sodium Phosphate 1.1mg (Equi.to 1473.435gm Moxifloxacin HCL & 297.391gm Dexamethasone Sodium Phosphate) | 54071 Numbers | 1       | Moxifloxacin Hydrochloride     | 1547.09 gram |
|                                                                                                                                                                                                                                                                                                                                                                 |               | 2       | Dexamethasone Sodium Phosphate | 312.26 gram  |

RA concerned may take further necessary action as per above decision of NC.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 86 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | MANGALAM ORGANICS LIMITED                   |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001371AM23                  |
| RA File Number               | 03AX04000956 AM23                           |
| Licence No and Date          | 0311015488/14/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------|---------------------------------------------|
| Case No.                | 87 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | GLENMARK PHARMACEUTICALS LIMITED            |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001372AM23                  |
| RA File Number          | 03AX04001157 AM23                           |
| Licence No and Date     | 0311015490/14/06/2022                       |

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Oct/202122/9 dated 15/10/2021** against advance authorization No. **0310838214 dated 11-09-2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                                                                                                                            | Qty.     | Sl. No. | Import items                 | Qty.              |
|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|------------------------------|-------------------|
| 1       | Clindamycin & Benzoyl Peroxide Gel 1percent/5percent ( Pack Size 25gm Pack )((Net Wt. of Import Item Sr. No. 1 is 25.00 Kgs. & Sr. No. 2 is 125.00 Kgs.)) | 1 Number | 1       | Clindamycin Phosphate USP    | 262.50 mg / pack  |
|         |                                                                                                                                                           |          | 2       | HYDROUS BENZOYL PEROXIDE USP | 1312.50 mg / pack |
| 2       | Clindamycin & Benzoyl Peroxide Gel 1percent/5percent ( Pack Size 35gm Pack )((Net Wt. of Import Item Sr. No. 1 is 35.00 Kgs. & Sr. No. 2 is 175.00 Kgs.)) | 1 Number | 1       | Clindamycin Phosphate USP    | 367.50 mg / pack  |

|   |                                                                                                                                                           |          |   |                              |                   |
|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|------------------------------|-------------------|
|   |                                                                                                                                                           |          | 2 | HYDROUS BENZOYL PEROXIDE USP | 1837.50 mg / pack |
| 3 | Clindamycin & Benzoyl Peroxide Gel 1percent/5percent ( Pack Size 50gm Pack )((Net Wt. of Import Item Sr. No. 1 is 40.00 Kgs. & Sr. No. 2 is 200.00 Kgs.)) | 1 Number | 1 | Clindamycin Phosphate USP    | 525.00 mg / pack  |
|   |                                                                                                                                                           |          | 2 | HYDROUS BENZOYL PEROXIDE USP | 2625.00 mg / pack |
| 4 | Adapalene & Benzoyl Peroxide Gel 0.1percent/2.5percent ( Pack Size 45gm Pack )((Net Wt. of Import Item Sr. No. 2 is 67.50 Kgs.))                          | 1 Number | 1 | HYDROUS BENZOYL PEROXIDE USP | 1181.25 mg / pack |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 88 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | INTAS PHARMACEUTICALS LIMITED               |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001386AM23                  |
| RA File Number          | 08AX04000368 AM23                           |
| Licence No and Date     | 0811005222/15/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Mar/202122/16 dated 08/04/2022** against advance authorization No. **0811002920 dated 20-10-2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                                                             | Qty.     | Sl. No. | Import items                               | Qty.<br>(for 1 Number Vial) |
|---------|--------------------------------------------------------------------------------------------|----------|---------|--------------------------------------------|-----------------------------|
| 1       | METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG) | 1 Number | 1       | METHOTREXATE EP / BP / IP / USP / PH. EUR. | 55.00 mg                    |

|   |                                                                                                                                                              |          |   |                                            |            |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|--------------------------------------------|------------|
| 2 | METHOTREXATE INJECTION BP 100MG/ML [5 ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100 MG)                                                               | 1 Number | 2 | METHOTREXATE EP / BP / IP / USP / PH. EUR. | 550.00 mg  |
| 3 | METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL](EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)                                                                 | 1 Number | 3 | METHOTREXATE EP / BP / IP / USP / PH. EUR. | 1100.00 mg |
| 4 | METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL](EACH ML CONTAINS: METHOTREXATE USP 25MG)                                                                      | 1 Number | 4 | METHOTREXATE EP / BP / IP / USP / PH. EUR. | 275.00 mg  |
| 5 | METHOTREXATE INJECTION BP 25MG/ML [20ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)                                                                  | 1 Number | 5 | METHOTREXATE EP / BP / IP / USP / PH. EUR. | 525.00 mg  |
| 6 | METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)                                                                  | 1 Number | 6 | METHOTREXATE EP / BP / IP / USP / PH. EUR. | 1050.00 mg |
| 7 | METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 100.430 KGS.]) | 1 Number | 7 | METHOTREXATE EP / BP / IP / USP / PH. EUR. | 5250.00 mg |

RA concerned may take further necessary action as per above decision of NC.

|                           |                                             |
|---------------------------|---------------------------------------------|
| Case No.                  | 89 / NC/3/MEET/Dec/202223/15                |
| Case Status               | Case Deferred                               |
| Party Name                | KAIRAV CHEMOFARBE INDUSTRIES LIMITED        |
| Meeting Number and Date   | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number            | HQRNORM APPLY 00001399AM23                  |
| RA File Number            | 03AX04001167 AM23                           |
| Licence No and Date       | 0311015523/15/06/2022                       |
| Norms Committee Decision: |                                             |

Deferred for comments of TE.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 90 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | SUN PHARMACEUTICAL INDUSTRIES LIMITED       |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001405AM23                  |
| RA File Number               | 05AX04000781 AM23                           |
| Licence No and Date          | 0511013234/15/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 91 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | INDOCO REMEDIES LIMITED                     |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001416AM23                  |
| RA File Number          | 03AX04001114 AM23                           |
| Licence No and Date     | 0311015585/16/06/2022                       |

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jan/202122/13 dated 21/01/2022** against advance authorization No. **0311006912 dated 13-09-2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                                                                                                                                                                                                                                                                            | Qty.              | Sl. No. | Import items      | Qty.                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---------|-------------------|--------------------------------|
| Ciprofloxacin and Dexamethasone Suspension USP ( 0.3% - 0.1 % ) 7.5ml Bottle.((Each ml Contains: CIPROFLOXACIN HYDROCHLORIDE EQU TO CIPROFLOXACIN BASE 3mg and DEXAMETHASONE 1mg per bottle of 7.5ml) (Each 7.5 ml Contains: Ciprofloxacin 22.5mg & Dexamethasone 7.5 mg) Net wt. Ciprofloxacin HCL 24.008 kgs & Dexamethasone 8.003 kgs) | 1067000<br>Number | 1       | Ciprofloxacin HCL | 27.6092.kg                     |
|                                                                                                                                                                                                                                                                                                                                           |                   | 2       | Dexamethasone     | 8.40315 kg                     |
|                                                                                                                                                                                                                                                                                                                                           |                   | 3       | Bottle            | Relevant as per packing policy |
|                                                                                                                                                                                                                                                                                                                                           |                   | 4       | Cap               | Relevant as per                |

|  |  |   |         |                                |
|--|--|---|---------|--------------------------------|
|  |  |   |         | packing policy                 |
|  |  | 5 | Dropper | Relevant as per packing policy |

RA concerned may take further necessary action as per above decision of NC.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 92 / NC/3/MEET/Dec/202223/15                |
| Case Status                  | Case Deferred                               |
| Party Name                   | AARTI DRUGS LIMITED                         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001418AM23                  |
| RA File Number               | 03AX04000671 AM23                           |
| Licence No and Date          | 0311014746/16/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                                                                                                                       |                                                    |
|-----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Case No.                                                                                                              | 93 / NC/3/MEET/Dec/202223/15                       |
| Case Status                                                                                                           | Case Approved                                      |
| Party Name                                                                                                            | VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED |
| Meeting Number and Date                                                                                               | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022        |
| HQ File Number                                                                                                        | HQRNORM APPLY 00001420AM23                         |
| RA File Number                                                                                                        | 03AX04001523 AM23                                  |
| Licence No and Date                                                                                                   | 0311015596/16/06/2022                              |
| Norms Committee Decision:                                                                                             |                                                    |
| The Committee considered the case as per agenda and it was decided to ratify adhoc norms as per <b>SION A - 412</b> . |                                                    |
| RA concerned may take further necessary action as per above decision of NC.                                           |                                                    |

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 94 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | GLOBAL CALCIUM PRIVATE LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001436AM23                  |

|                                                                                                                                                                                                 |                       |         |                             |         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------|-----------------------------|---------|
| RA File Number                                                                                                                                                                                  | 07AX04000278 AM23     |         |                             |         |
| Licence No and Date                                                                                                                                                                             | 0711004325/16/06/2022 |         |                             |         |
| Norms Committee Decision:                                                                                                                                                                       |                       |         |                             |         |
| The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                       |         |                             |         |
| Export product                                                                                                                                                                                  | Qty.                  | Sl. No. | Import items                | Qty.    |
| MAGNESIUM BISGLYCINATE /<br>MAGNESIUM GLYCINE<br>COMPLEX                                                                                                                                        | 1 kg                  | 1       | GLYCINE - ANY GRADE         | 0.97 kg |
|                                                                                                                                                                                                 |                       | 2       | MAGNESIUM OXIDE - ANY GRADE | 0.26 kg |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                     |                       |         |                             |         |

|                                                                                                                                                                                                                                                                                                                                                                                                              |                                             |         |                                           |          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------|-------------------------------------------|----------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                     | 95 / NC/3/MEET/Dec/202223/15                |         |                                           |          |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                  | Case Approved                               |         |                                           |          |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                   | OPTIMUS DRUGS PRIVATE LIMITED               |         |                                           |          |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |         |                                           |          |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                               | HQRNORM APPLY 00001441AM23                  |         |                                           |          |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                               | 09AX04000232 AM23                           |         |                                           |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                          | 0911003192/17/06/2022                       |         |                                           |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                    |                                             |         |                                           |          |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Nov/202223/12 dated 18/11/2022</b> against advance authorization No. <b>0911002929 dated 02/05/2022</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |         |                                           |          |
| Export product                                                                                                                                                                                                                                                                                                                                                                                               | Qty.                                        | Sl. No. | Import items                              | Qty.     |
| (1R,2R)-2-Amino-6-(4-Nitrophenyl)-1-Phenylhex-5-yn-1-ol Hydrochloride                                                                                                                                                                                                                                                                                                                                        | 1 kg                                        | 1       | Di-Tert-Butyl Dicarboxate (Boc Anhydride) | 3.16 kg  |
|                                                                                                                                                                                                                                                                                                                                                                                                              |                                             | 2       | CDX-034 Lyophilized Enzyme Powder         | 0.012 kg |

|  |  |   |                                                                             |          |
|--|--|---|-----------------------------------------------------------------------------|----------|
|  |  | 3 | Beta-Nicotinamide Adenine dinucleotide phosphate Sodium salt (beta-NADP-Na) | 0.008 kg |
|  |  | 4 | N-Heptane                                                                   | 3.00 kg  |
|  |  | 5 | Tetra Hydro Furan                                                           | 5.00 kg  |
|  |  | 6 | Iso Propyl Alcohol (IPA)                                                    | 10.00 kg |
|  |  | 7 | Methyl Tertiary-Butyl Ether (MTBE)                                          | 3.50 kg  |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 96 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | GLOBAL CALCIUM PRIVATE LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001460AM23                  |
| RA File Number          | 07AX04000125 AM23                           |
| Licence No and Date     | 0711004348/17/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **4/82-ALC4/2018 dated 19.06.2018** against advance authorization No. **0710112735 dated 23.01.2018**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export Product                      | Qty. | Import Items          | Qty.     |
|---------|-------------------------------------|------|-----------------------|----------|
| 1       | MAGNESIUM LACTATE GLUCONATE         | 1 kg | GLUCONO DELTA LACTONE | 0.755 kg |
| 2       | ZINC GLUCONATE (Eur.Ph/USP)         | 1 kg | GLUCONO DELTA LACTONE | 0.945 kg |
| 3       | MAGNESIUM GLUCONATE<br>(Eur.Ph/USP) | 1 kg | GLUCONO DELTA LACTONE | 0.945 kg |

|   |                                     |      |                       |          |
|---|-------------------------------------|------|-----------------------|----------|
| 4 | POTASSIUM GLUCONATE (USP)           | 1 kg | GLUCONO DELTA LACTONE | 0.930 kg |
| 5 | FERROUS GLUCONATE (BP/EP/USP)       | 1 kg | GLUCONO DELTA LACTONE | 0.887 kg |
| 6 | MANGANESE GLUCONATE (Eur.Ph/USP)    | 1 kg | GLUCONO DELTA LACTONE | 0.945 kg |
| 7 | CALCIUM MAGNESIUM LACTATE GLUCONATE | 1 kg | GLUCONO DELTA LACTONE | 0.831 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 97 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | MAIVA PHARMA PRIVATE LIMITED                |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001442AM23                  |
| RA File Number          | 07AX04000349 AM23                           |
| Licence No and Date     | 0711004326/17/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09/09/2022** against advance authorization No. **0711002867 dated 20/01/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export Product                                                                                                                                           | Qty.     | Sl. No. | Import Items                                | Qty.                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|---------------------------------------------|--------------------------------|
| Sodium Bicarbonate Injection 84mg/mL -50mL Vial(Sodium Bicarbonate as bulk drug filled in 50mL Vial and capped with 20mm Bromobutyl Grey Rubber Stopper) | 1 Number | 1       | 20mm Bromobutyl Grey R/S- C5474 6720GC 6TP3 | Relevant as per packing policy |

RA concerned may take further necessary action as per above decision of NC.

|          |                              |
|----------|------------------------------|
| Case No. | 98 / NC/3/MEET/Dec/202223/15 |
|----------|------------------------------|

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case Status             | Case Approved                               |
| Party Name              | MAIVA PHARMA PRIVATE LIMITED                |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001444AM23                  |
| RA File Number          | 07AX04000348 AM23                           |
| Licence No and Date     | 0711004297/17/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09/09/2022** against advance authorization No. **0711002867 dated 20/01/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export Product                                                                                                                                                                                                  | Qty.     | Sl. No. | Import Items                                                               | Qty.                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|----------------------------------------------------------------------------|--------------------------------|
| Sodium Bicarbonate Injection 84mg/mL -50mL Vial(Sodium Bicarbonate as bulk drug filled in 50mL Vial and capped with 20mm Bromobutyl Grey Rubber Stopper along with 20mm White color Matte finish Flip Off seal) | 1 Number | 1       | 20FO LQ 3766 WHITE MATTE TOP(20mm White Color Matte Finish Flip Off Seals) | Relevant as per packing policy |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 99 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                               |
| Party Name              | AMOLI ORGANICS PRIVATE LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001446AM23                  |
| RA File Number          | 03AX04000853 AM23                           |
| Licence No and Date     | 0311015623/17/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Apr/202223/1 dated 29/04/2022** against advance authorization No. **0311009329 dated 16-12-2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export Product                          | Qty. | Sl. No. | Import Items                                                                                                                                           | Qty.    |
|-----------------------------------------|------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| Rosuvastatin Calcium USP / BP / EP / IH | 1 kg | 1       | Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate | 1.30 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                                    |
|-------------------------|----------------------------------------------------|
| Case No.                | 100 / NC/3/MEET/Dec/202223/15                      |
| Case Status             | Case Approved                                      |
| Party Name              | VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022        |
| HQ File Number          | HQRNORM APPLY 00001454AM23                         |
| RA File Number          | 03AX04001519 AM23                                  |
| Licence No and Date     | 0311015627/17/06/2022                              |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **8/82-ALC4/2019 dated 20.09.2019** against advance authorization No. **0710114616 dated 04.03.2019**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                          | Qty.     | Sl. No. | Import items              | Qty.                       |
|---------|-----------------------------------------|----------|---------|---------------------------|----------------------------|
| 1       | CLINDAMYCIN HYDRCHLORIDE 150MG CAPSULES | 1 Number | 1       | Clindamycin Hydrochloride | 173.53 mg / 150 mg capsule |
| 2       | CLINDAMYCIN HYDRCHLORIDE 300MG CAPSULES | 1 Number | 1       | Clindamycin Hydrochloride | 347.06 mg / 300 mg capsule |

RA concerned may take further necessary action as per above decision of NC.

|             |                               |
|-------------|-------------------------------|
| Case No.    | 101 / NC/3/MEET/Dec/202223/15 |
| Case Status | Case Approved                 |

|                         |                                             |
|-------------------------|---------------------------------------------|
| Party Name              | MAIVA PHARMA PRIVATE LIMITED                |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001457AM23                  |
| RA File Number          | 07AX04000379 AM23                           |
| Licence No and Date     | 0711004345/17/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Apr/202223/1 dated 29/04/2022** against advance authorization No. **0711002685 dated 20-12-2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export Product                                                                                                                                                                                  | Qty.     | Sl. No. | Import Items                          | Qty.                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|---------------------------------------|--------------------------------|
| Sodium Chloride Injection USP 90mg per 10mL Vial. (10mL Vial - filled with 90mg of Sodium Chloride as bulk drug filled in 10mL Vial and capped with 13mm GreySerum ChlorobutyI Rubber Stopper ) | 1 Number | 1       | 10ml Unprinted Clear Glass Vial Empty | Relevant as per packing policy |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 102 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | GLOBAL CALCIUM PRIVATE LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001458AM23                  |
| RA File Number          | 07AX04000280 AM23                           |
| Licence No and Date     | 0711004346/17/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jul/202122/4 dated 15.07.2021** against advance authorization No. **0710112638 dated 04.01.2018**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                                                               | Qty. | Sl. No. | Import items                     | Qty.     |
|---------|----------------------------------------------------------------------------------------------|------|---------|----------------------------------|----------|
| 1       | MAGNESIUM CITRATE (USP/<br>NONAHYDRATE Eur.Ph/<br>ANHYDROUS Eur.Ph/<br>DODECAHYDRATE Eur.Ph) | 1 kg | 1       | CITRIC ACID - ANY GRADE          | 1.001 kg |
|         |                                                                                              |      | 2       | MAGNESIUM CARBONATE<br>ANY GRADE | 0.730 kg |
| 2       | CALCIUM CITRATE(USP)                                                                         | 1 kg | 1       | CITRIC ACID - ANY GRADE          | 0.816 kg |
|         |                                                                                              |      | 2       | CALCIUM CARBONATE                | 0.708 kg |
| 3       | ZINC CITRATE(USP)                                                                            | 1 kg | 1       | CITRIC ACID - ANY GRADE          | 0.880 kg |
| 4       | POTASSIUM CITRATE<br>(BP/Eur.Ph/ USP)                                                        | 1 kg | 1       | CITRIC ACID - ANY GRADE          |          |

RA concerned may take further necessary action as per above decision of NC.

|                                                                                                                                                                                                                                                                                                                                                   |                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                          | 103 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                                                                                                                                                                       | Case Deferred                               |
| Party Name                                                                                                                                                                                                                                                                                                                                        | GLOBAL CALCIUM PRIVATE LIMITED              |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                           | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                    | HQRNORM APPLY 00001459AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                    | 07AX04000281 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                               | 0711004347/17/06/2022                       |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:</p> <p><b>i. COA report of Export Product and Import Item.</b></p> <p><b>ii. Indigenous item to use in manufacturing export item and to fill the same in Appendix 4E.</b></p> |                                             |

|             |                                     |
|-------------|-------------------------------------|
| Case No.    | 104 / NC/3/MEET/Dec/202223/15       |
| Case Status | Case Approved                       |
| Party Name  | AROHEMA INGREDIENTS PRIVATE LIMITED |

|                                                                                                                                                                                                 |                                             |         |                     |           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------|---------------------|-----------|
| Meeting Number and Date                                                                                                                                                                         | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |         |                     |           |
| HQ File Number                                                                                                                                                                                  | HQRNORM APPLY 00001494AM23                  |         |                     |           |
| RA File Number                                                                                                                                                                                  | 26AX04000023 AM23                           |         |                     |           |
| Licence No and Date                                                                                                                                                                             | 2611000623/20/06/2022                       |         |                     |           |
| Norms Committee Decision:                                                                                                                                                                       |                                             |         |                     |           |
| The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |         |                     |           |
| Export product                                                                                                                                                                                  | Qty.                                        | Sl. No. | Import items        | Qty.      |
| ORCANOX                                                                                                                                                                                         | 1 kg                                        | 1       | SCLAREOLIDE         | 1.1768 kg |
|                                                                                                                                                                                                 |                                             | 2       | TERT - AMYL ALCOHOL | 1.00 kg   |
| <b>RA concerned may take further necessary action as per above decision of NC.</b>                                                                                                              |                                             |         |                     |           |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 105 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | YASHO INDUSTRIES LIMITED                    |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001521AM23                  |
| RA File Number               | 03AX04001765 AM23                           |
| Licence No and Date          | 0311015682/20/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                           |                                             |
|---------------------------|---------------------------------------------|
| Case No.                  | 106 / NC/3/MEET/Dec/202223/15               |
| Case Status               | Case Approved                               |
| Party Name                | MAIVA PHARMA PRIVATE LIMITED                |
| Meeting Number and Date   | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number            | HQRNORM APPLY 00001522AM23                  |
| RA File Number            | 07AX04000389 AM23                           |
| Licence No and Date       | 0711004350/21/06/2022                       |
| Norms Committee Decision: |                                             |

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0711003985 dated 19/05/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                                                                                                                                                              | Qty.              | Sl. No. | Import items                                                                         | Qty.                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---------|--------------------------------------------------------------------------------------|--------------------------------|
| Prochlorperazine Edisylate Injection 10mg/2mL(Prochlorperazine Edisylate Injection 10mg, 2mL vial - 10 mg of bulk drug filled in 2 mL vial and capped with 13mm Rubber Stopper & 13mm Omniflexplus Coated(Dark Grey) Seals) | 307800<br>Numbers | 1       | 110010718 V9239 FM259/0 FLCO 015 (13mm Omniflexplus Coated BB R/S-RFS V9239 FM259/0) | Relevant as per Packing Policy |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 107 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | AUORE LIFE SCIENCES PRIVATE LIMITED         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001527AM23                  |
| RA File Number          | 09AX04000227 AM23                           |
| Licence No and Date     | 0911003213/21/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Mar/2022122/16 dated 08/04/2022** against advance authorization No. **0911001704 dated 11-10-2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                           | Qty. | Sl. No. | Import items   | Qty.     |
|------------------------------------------|------|---------|----------------|----------|
| VILDAGLIPTIN<br>(Pharmaceutical product) | 1 kg | 1       | L Proline      | 0.855 kg |
|                                          |      | 2       | Amantadine HCL | 0.904 kg |

|  |  |   |                   |         |
|--|--|---|-------------------|---------|
|  |  | 3 | Dimethylformamide | 0.50 kg |
|--|--|---|-------------------|---------|

RA concerned may take further necessary action as per above decision of NC.

|                         |                                              |
|-------------------------|----------------------------------------------|
| Case No.                | 108 / NC/3/MEET/Dec/202223/15                |
| Case Status             | Case Approved                                |
| Party Name              | PUNJAB CHEMICALS AND CROP PROTECTION LIMITED |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022  |
| HQ File Number          | HQRNORM APPLY 00001530AM23                   |
| RA File Number          | 03AX04001714 AM23                            |
| Licence No and Date     | 0311015686/21/06/2022                        |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jun/2022223/5 dated 08/07/2022** against advance authorization No. **0311001236 dated 28/01/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                | Qty. | Sl. No. | Import items          | Qty.     |
|-------------------------------|------|---------|-----------------------|----------|
| TRIMETHYL SULFOXONIUM BROMIDE | 1 kg | 1       | Dimethyl Sulfoxide    | 0.932 kg |
|                               |      | 2       | Trimetyl Orthoformate | 0.018 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 109 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | GLOBAL CALCIUM PRIVATE LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001548AM23                  |
| RA File Number          | 07AX04000277 AM23                           |
| Licence No and Date     | 0711004391/21/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jun/2022122/2 dated 02/07/2021** against advance authorization No. **0711000943 dated 23/04/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | EXPORT PRODUCT             | QTY. | Sl. No. | IMPORT ITEMS      | QTY.     |
|---------|----------------------------|------|---------|-------------------|----------|
| 1.      | CALCIUM LACTOBIONATE       | 1 kg | 1.      | CALCIUM CARBONATE | 0.172 kg |
|         |                            |      | 2.      | LACTOSE           | 1.16 kg  |
| 2.      | CALCIUM BROMO LACTOBIONATE | 1 kg | 1.      | CALCIUM CARBONATE | 0.360 kg |
|         |                            |      | 2.      | LACTOSE           | 1.021 kg |
|         |                            |      | 3.      | HYDROBROMIC ACID  | 0.510 kg |
| 3.      | CALCIUM GLUBIONATE         | 1 kg | 1.      | CALCIUM CARBONATE | 0.140 kg |
|         |                            |      | 2.      | LACTOSE           | 0.829 kg |
|         |                            |      | 3.      | CALCIUM GLUCONATE | 0.42 kg  |
| 4.      | LACTOBIONIC ACID           | 1 kg | 1.      | CALCIUM CARBONATE | 0.234 kg |
|         |                            |      | 2.      | LACTOSE           | 1.58 kg  |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 110 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | BRAWN LABORATORIES LIMITED                  |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001556AM23                  |
| RA File Number          | 05AX04000865 AM23                           |
| Licence No and          | 0511013337/21/06/2022                       |

|                                                                                                                                                                                                                                                                                                                                                                                                                     |          |         |                     |        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|---------------------|--------|
| Date                                                                                                                                                                                                                                                                                                                                                                                                                |          |         |                     |        |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                           |          |         |                     |        |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Mar/2022122/15 dated 17/03/2022</b> against advance authorization No. <b>0311000200 dated 16/12/2020</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |          |         |                     |        |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                      | Qty.     | Sl. No. | Import items        | Qty.   |
| DOXYCYCLINE CAPSULES 100 MG((HARD GELATINE CAPSULES CONTAINING YELLOW GRANULAR POWDER))                                                                                                                                                                                                                                                                                                                             | 1 Number | 1       | DOXYCYCLINE HYCLATE | 117 mg |
| <p>RA concerned may take further necessary action as per above decision of NC.</p>                                                                                                                                                                                                                                                                                                                                  |          |         |                     |        |

|                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                  |             |         |                           |            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------|---------------------------|------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                      | 111 / NC/3/MEET/Dec/202223/15                                                                                                                                                                    |             |         |                           |            |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                   | Case Approved                                                                                                                                                                                    |             |         |                           |            |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                    | J B CHEMICALS AND PHARMACEUTICALS LIMITED                                                                                                                                                        |             |         |                           |            |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                       | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022                                                                                                                                                      |             |         |                           |            |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                | HQRNORM APPLY 00001568AM23                                                                                                                                                                       |             |         |                           |            |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                | 03AX04001806 AM23                                                                                                                                                                                |             |         |                           |            |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                           | 0311015747/22/06/2022                                                                                                                                                                            |             |         |                           |            |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                  |             |         |                           |            |
| <p>The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Nov/202223/12 dated 18/11/2022</b> against advance authorization No. <b>0311012790 dated 14/03/2022</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                                                                                                                                                                                                  |             |         |                           |            |
| Sl. No.                                                                                                                                                                                                                                                                                                                                                                                                                       | Export product                                                                                                                                                                                   | Qty.        | Sl. No. | Import items              | Qty.       |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                             | Benzydamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and(all other flavours. Each lozenge contains (i) Benzydamine Hydrochloride-3mg (ii) | 1000 Number | 1.      | Benzydamine Hydrochloride | 3.06 gram  |
|                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                  |             | 2       | Cetylpyridinium Chloride  | 1.356 gram |

|                                                                             |                                                                                                                                                                                                                                                                                             |                |    |                           |            |
|-----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----|---------------------------|------------|
|                                                                             | Cetylpyridinium Chloride- 1.33mg (iii)<br>Isomalt ST-M - 2586mg. Net content (i)<br>33.333 Kgs (ii) 14.778 Kgs (iii)<br>28733.356 Kgs.)                                                                                                                                                     |                | 3  | Isomalt ST-M              | 2586 gram  |
| 2                                                                           | Benzydamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg. Net content (i) 21.333 Kgs. (ii) 18389.439 Kgs.) | 1000<br>Number | 4  | Benzydamine Hydrochloride | 3.06 gram  |
|                                                                             |                                                                                                                                                                                                                                                                                             |                | 5  | Isomalt ST-M              | 2586 gram  |
| 3                                                                           | Benzydamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride-(3mg (ii) Isomalt ST-M - 2586mg. Net content (i) 12 Kgs. (ii) 10344 Kgs.)                                                                                              | 1000<br>Number | 6  | Benzydamine Hydrochloride | 3.06 gram  |
|                                                                             |                                                                                                                                                                                                                                                                                             |                | 7  | Isomalt ST-M              | 2586 gram  |
| 4                                                                           | Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 13.333 Kg (ii) 25924.878 Kg)                                          | 1000<br>Number | 8  | Cetylpyridinium Chloride  | 1.356 gram |
|                                                                             |                                                                                                                                                                                                                                                                                             |                | 9  | Isomalt ST-M              | 2586 gram  |
| 5                                                                           | Cetylpyridinium Chloride And Benzydamine Hydrochloride Antiseptic Lozenges Sugar Free. Each lozenge contains (i) Cetylpyridinium Chloride-1mg (ii) Isomalt ST-M - 2586mg. Net content (i) 5.22 Kg (ii) 13498.92 Kg)                                                                         | 1000<br>Number | 9  | Cetylpyridinium Chloride  | 1.02 gram  |
|                                                                             |                                                                                                                                                                                                                                                                                             |                | 10 | Isomalt ST-M              | 2586 gram  |
| RA concerned may take further necessary action as per above decision of NC. |                                                                                                                                                                                                                                                                                             |                |    |                           |            |

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|-------------------------|---------------------------------------------------|
| Case No.                | 112 / NC/3/MEET/Dec/202223/15                     |
| Case Status             | Case Approved                                     |
| Party Name              | BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022       |
| HQ File Number          | HQRNORM APPLY 00001597AM23                        |

|                                                                                                                                                                                                 |                       |         |                     |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------|---------------------|--------------|
| RA File Number                                                                                                                                                                                  | 03AX04001819 AM23     |         |                     |              |
| Licence No and Date                                                                                                                                                                             | 0311015779/22/06/2022 |         |                     |              |
| Norms Committee Decision:                                                                                                                                                                       |                       |         |                     |              |
| The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                       |         |                     |              |
| Export Product                                                                                                                                                                                  | Qty.                  | Sl. No. | Import items        | Qty.         |
| CASPOFUNGIN ACETATE FOR INJECTION 50MG. Net content of CASPOFUNGIN ACETATE 650 GMS                                                                                                              | 1 Vial                | 1       | CASPOFUNGIN ACETATE | 55 mg / Vial |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                     |                       |         |                     |              |

|                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                       |                |        |                           |            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------|---------------------------|------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                | 113 / NC/3/MEET/Dec/202223/15                                                                                                                                         |                |        |                           |            |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                             | Case Approved                                                                                                                                                         |                |        |                           |            |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                              | J B CHEMICALS AND PHARMACEUTICALS LIMITED                                                                                                                             |                |        |                           |            |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                 | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022                                                                                                                           |                |        |                           |            |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                          | HQRNORM APPLY 00001569AM23                                                                                                                                            |                |        |                           |            |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                          | 03AX04001807 AM23                                                                                                                                                     |                |        |                           |            |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                     | 0311015749/22/06/2022                                                                                                                                                 |                |        |                           |            |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                       |                |        |                           |            |
| The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Nov/202223/12 dated 18/11/2022</b> against advance authorization No. <b>0311012790 dated 14/03/2022</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                                                                                                                                                       |                |        |                           |            |
| Sl. No.                                                                                                                                                                                                                                                                                                                                                                                                                 | Export product                                                                                                                                                        | Qty.           | Sl. No | Import items              | Qty.       |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                       | Benzydamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and(other flavours. Each lozenge contains (i) Benzydamine | 1000<br>Number | 1.     | Benzydamine Hydrochloride | 3.06 gram  |
|                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                       |                | 2      | Cetylpyridinium           | 1.356 gram |

|                                                                             |                                                                                                                                                                                                                                                                                                                |                |    |                           |            |
|-----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----|---------------------------|------------|
|                                                                             | Hydrochloride-3mg (ii) Cetylpyridinium Chloride- 1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 31.034 Kgs (ii) 13.759 Kgs (iii) 26751.736 Kgs.)                                                                                                                                                          |                |    | Chloride                  |            |
|                                                                             |                                                                                                                                                                                                                                                                                                                |                | 3  | Isomalt ST-M              | 2586 gram  |
| 2                                                                           | Benzydamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-Inflammatory, Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg. Net content (i) 25.926 Kgs. (ii) 22348.129 Kgs.) | 1000<br>Number | 4  | Benzydamine Hydrochloride | 3.06 gram  |
|                                                                             |                                                                                                                                                                                                                                                                                                                |                | 5  | Isomalt ST-M              | 2586 gram  |
| 3                                                                           | Benzydamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free.(Each lozenge contains (i) Benzydamine Hydrochloride- 3mg (ii) Isomalt ST-M - 2586mg. Net content (i) 13.333 Kgs. (ii) 11493.343 Kgs.)                                                                                                         | 1000<br>Number | 6  | Benzydamine Hydrochloride | 3.06 gram  |
|                                                                             |                                                                                                                                                                                                                                                                                                                |                | 7  | Isomalt ST-M              | 2586 gram  |
| 4                                                                           | Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 1.968 Kg (ii) 3825.997 Kg.)                                                              | 1000<br>Number | 8  | Cetylpyridinium Chloride  | 1.356 gram |
|                                                                             |                                                                                                                                                                                                                                                                                                                |                | 9  | Isomalt ST-M              | 2586 gram  |
| 5                                                                           | Cetylpyridinium Chloride And Benzydamine Hydrochloride Antiseptic Lozenges Sugar Free.(Each lozenge contains (i) Cetylpyridinium Chloride- 1 mg (ii) Isomalt ST-M - 2586mg. Net content (i) 1.333 Kg (ii) 3448.028 Kg)                                                                                         | 1000<br>Number | 9  | Cetylpyridinium Chloride  | 1.02 gram  |
|                                                                             |                                                                                                                                                                                                                                                                                                                |                | 10 | Isomalt ST-M              | 2586 gram  |
| RA concerned may take further necessary action as per above decision of NC. |                                                                                                                                                                                                                                                                                                                |                |    |                           |            |

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|-------------------------|---------------------------------------------|
| Case No.                | 114 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | SUN PHARMACEUTICAL INDUSTRIES LIMITED       |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |

|                     |                            |
|---------------------|----------------------------|
| HQ File Number      | HQRNORM APPLY 00001570AM23 |
| RA File Number      | 05AX04000861 AM23          |
| Licence No and Date | 0511013343/22/06/2022      |

Norms Committee Decision:

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Mar/202223/16 dated 08/04/2022** against advance authorization No. **0511005404 dated 13/10/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                                                                                                                                                    | Qty.          | Sl. No | Import items                    | Qty.      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|--------|---------------------------------|-----------|
| Brinzolamide Ophthalmic Suspension, 1% w/v 5ml (Sterile Eye Drops) (BRINOLAR / BRAZTEC)((Each ml contains Brinzolamide equivalent to Brinzolamide Micronized Sterile 10 mg (Equivalent to 1300 Gm of Bulk Drug),) | 26000 Numbers | 1      | Brinzolamide Micronized Sterile | 1326 gram |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 115 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | SMS PHARMACEUTICALS LIMITED                 |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001577AM23                  |
| RA File Number          | 09AX04000241 AM23                           |
| Licence No and Date     | 0911003220/22/06/2022                       |

Norms Committee Decision:

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/9 dated 07/10/2022** against advance authorization No. **0911002637 dated 08/03/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product | Qty. | Sl. No. | Import items                     | Qty.     |
|----------------|------|---------|----------------------------------|----------|
| SITAGLIPTIN    | 1 kg | 1       | 2,4,5 TRIFLUOROPHENYLACETIC ACID | 1.146 kg |

|                                                                             |    |                                                                                        |          |
|-----------------------------------------------------------------------------|----|----------------------------------------------------------------------------------------|----------|
| HYDROCHLORIDE                                                               | 2  | MELDRUM ACID                                                                           | 0.88 kg  |
|                                                                             | 3  | 3-(TERIFLUOROMETHYL)-5,6,7,8-TETRAHYDRI-[1,2,4] TRIAZOLO[4,3-a] PYRAZINE HYDROCHLORIDE | 0.75 kg  |
|                                                                             | 4  | DI-TERTIARY BUTYL DICARBONATE (DIBOC)                                                  | 1.50 kg  |
|                                                                             | 5  | TETRAHYDROFURAN                                                                        | 1.50 kg  |
|                                                                             | 6  | ISO PROPYL ALCOHOL                                                                     | 5.50 kg  |
|                                                                             | 7  | METHYL DI CHLORIDE                                                                     | 12.18 kg |
|                                                                             | 8  | METHANOL                                                                               | 3.12 kg  |
|                                                                             | 9  | N-HEPTANE                                                                              | 1.80 kg  |
|                                                                             | 10 | TERTIARY BUTANOL (T-BUTANOL)                                                           | 1.78 kg  |
| RA concerned may take further necessary action as per above decision of NC. |    |                                                                                        |          |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 116 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Case Approved                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                     | SATYADIVIS PHARMACEUTICALS PRIVATE LIMITED  |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                        | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                 | HQRNORM APPLY 00001579AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 09AX04000240 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                            | 0911003221/22/06/2022                       |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Oct/202122/10 dated 12/11/2021</b> against advance authorization No. <b>0910069294 dated 01/10/2020</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                                             |

| Export product | Qty. | Sl. No. | Import items                  | Qty.     |
|----------------|------|---------|-------------------------------|----------|
| FLUOXETINE HCL | 1 kg | 1       | BENZALDEHYDE                  | 0.83 kg  |
|                |      | 2       | PALLADIUM                     | 0.005 kg |
|                |      | 3       | ACETOPHENONE                  | 0.847 kg |
|                |      | 4       | DIMETHYL SULPHOXIDE           | 2.29 kg  |
|                |      | 5       | PARAFORMALDEHYDE              | 0.253 kg |
|                |      | 6       | PARA CHLORO BENZO TRIFLOURIDE | 1.054 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 117 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | SENTISS PHARMA PRIVATE LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001585AM23                  |
| RA File Number          | 05AX04000883 AM23                           |
| Licence No and Date     | 0511013369/22/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/May/202223/4 dated 17/06/2022** against advance authorization No. **0511002009 dated 31/03/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                             | Qty.         | Sl. No. | Import items         | Qty.    |
|------------------------------------------------------------|--------------|---------|----------------------|---------|
| Brimonidine Tartrate 0.1% Eye Drops Solution 5ml Santabrim | 157060 Vials | 1       | Brimonidine Tartrate | 0.80 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 118 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | SENTISS PHARMA PRIVATE LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001586AM23                  |
| RA File Number          | 05AX04000882 AM23                           |
| Licence No and Date     | 0511013370/22/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Apr/202223/1 dated 29/04/2022** against advance authorization No. **0511006792 dated 10/12/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                      | Qty.   | Sl. No. | Import items | Qty.            |
|-------------------------------------------------------------------------------------|--------|---------|--------------|-----------------|
| Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml | 1 Vial | 1       | Brinzolamide | 51.00 mg / Vial |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 119 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | PIRAMAL PHARMA LIMITED                      |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001593AM23                  |
| RA File Number          | 03AX04001832 AM23                           |
| Licence No and Date     | 0311015776/22/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0311013612 dated 05/04/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export Product                                                                                                                                                      | Qty.            | Sl. No. | Import items                                                         | Qty.                           |
|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------|----------------------------------------------------------------------|--------------------------------|
| 1       | Atorvastatin Calcium Tablets USP 10mg((Net wt. of Import Sr. No. 1 is 495.945kgs, Sr. No. 2 is 2746.71kg, Sr. No. 3 is 779.985kg, Sr. No. 4 is 505000 Nos.))        | 1 Number Tablet | 1       | Atorvastatin Calcium Propylene Glycol Solvate USP                    | 11.415 mg                      |
|         |                                                                                                                                                                     |                 | 2       | Microcrystalline Cellulose (MCC) NF (Avicel PH 102)                  | 64.578 mg                      |
|         |                                                                                                                                                                     |                 | 3       | Calcium Acetate                                                      | 18.049 mg                      |
|         |                                                                                                                                                                     |                 | 4       | Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent) | Relevant as per packing policy |
| 2       | Atorvastatin Calcium Tablets USP 20mg((Net wt. of Import Sr. No. 1 is 198.378kgs, Sr. No. 2 is 1102.572kg, Sr. No. 3 is 312.93kg, Sr. No. 4 is 101000 Nos.))        | 1 Number Tablet | 1       | Atorvastatin Calcium Propylene Glycol Solvate USP                    | 22.830 mg                      |
|         |                                                                                                                                                                     |                 | 2       | Microcrystalline Cellulose (MCC) NF (Avicel PH 102)                  | 129.427 mg                     |
|         |                                                                                                                                                                     |                 | 3       | Calcium Acetate                                                      | 36.090 mg                      |
|         |                                                                                                                                                                     |                 | 4       | Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent) | Relevant as per packing policy |
| 3       | Atorvastatin Calcium Tablets USP 40mg((Net wt. of Import Sr. No. 1 is 4364.316kgs, Sr. No. 2 is 24172.83kg, Sr. No. 3 is 6864.264.24kg, Sr. No. 4 is 1111000 Nos.)) | 1 Number Tablet | 1       | Atorvastatin Calcium Propylene Glycol Solvate USP                    | 45.595 mg                      |
|         |                                                                                                                                                                     |                 | 2       | Microcrystalline Cellulose (MCC) NF (Avicel PH 102)                  | 258.08 mg                      |
|         |                                                                                                                                                                     |                 | 3       | Calcium Acetate                                                      | 71.963 mg                      |
|         |                                                                                                                                                                     |                 | 4       | Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent) | Relevant as per packing policy |
| 4       | Atorvastatin Calcium Tablets USP 80mg((Net wt. of Import Sr. No. 1 is 2063.131kgs, Sr. No. 2 is 11482.123kg, Sr. No. 3 is 3258.146kg, Sr. No. 4 is 262600           | 1 Number Tablet | 1       | Atorvastatin Calcium Propylene Glycol Solvate USP                    | 91.20 mg                       |
|         |                                                                                                                                                                     |                 | 2       | Microcrystalline Cellulose (MCC) NF (Avicel PH 102)                  | 518.206 mg                     |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|--|---|----------------------------------------------------------------------|--------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                            | Nos.)) |  | 3 | Calcium Acetate                                                      | 144.929 mg                     |
|                                                                                                                                                                                                                                                                                                                                                                            |        |  | 4 | Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent) | Relevant as per packing policy |
| <b>Note: The above norms are valid only for subject to fulfillment of following conditions:</b><br><br><b>1. Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application) of Apotex Corp, US. Agent for Apotex Inc., Candada.</b><br><b>2. Export to USA only.</b><br><b>3. Firm holding Certificate of Manufacturing Exclusivity.</b> |        |  |   |                                                                      |                                |

RA concerned may take further necessary action as per above decision of NC.

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|------------------------------|---------------------------------------------|
| Case No.                     | 120 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | INTAS PHARMACEUTICALS LIMITED               |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001604AM23                  |
| RA File Number               | 08AX04000401 AM23                           |
| Licence No and Date          | 0811005305/23/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 121 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | INTAS PHARMACEUTICALS LIMITED               |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001605AM23                  |
| RA File Number               | 08AX04000497 AM23                           |
| Licence No and Date          | 0811005314/23/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------|-------------------------------|
| Case No.    | 122 / NC/3/MEET/Dec/202223/15 |
| Case Status | Case Approved                 |
| Party Name  | CIPLA LIMITED                 |

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|-------------------------|---------------------------------------------|
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001629AM23                  |
| RA File Number          | 03AX04001871 AM23                           |
| Licence No and Date     | 0311015826/24/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jan/202122/13 dated 21/01/2022** against advance authorization No. **0311005772 dated 30/07/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                                                                                                                                                                                                                                                                                      | Qty.     | Sl. No. | Import items        | Qty.     |
|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|---------------------|----------|
| 1       | Telmisartan and Amlodipine Tablets 40/10mg / Each uncoated tablets contains : Telmisartan 40 mg(Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is 2020.800 Kgs. Net wt of Amlodipine Besilate is 300.000 Kgs.)   | 1 Number | 1       | Amlodipine Besilate | 10.20 mg |
| 2       | Telmisartan and Amlodipine Tablets 80/10mg / Each uncoated tablets contains : Telmisartan 80 mg(Telmisartan 80 mg equivalent to Telmisartan granules 134.72mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is 10777.600 Kgs. Net wt of Amlodipine Besilate is 800.000 Kgs.) | 1 Number | 2       | Amlodipine Besilate | 10.20 mg |
| 3       | Telmisartan and Amlodipine Tablets 40/5mg / Each uncoated tablets contains : Telmisartan 40 mg(Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 5mg Net wt of Telmisartan Granules is 6286.933 Kgs.                                                    | 1 Number | 3       | Amlodipine Besilate | 5.10 mg  |

|   |                                                                                                                                                                                                                                                                                                                   |          |   |                     |         |
|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|---------------------|---------|
|   | Net wt of Amlodipine Besilate is 466.667 Kgs.)                                                                                                                                                                                                                                                                    |          |   |                     |         |
| 4 | Telmisartan and Amlodipine Tablets 80/5mg / Each uncoated tablets contains : Telmisartan 80 mg(Telmisartan 80 mg equivalent to Telmisartan granules 134.72mg Amlodipine Besilate equivalent to Amlodipine USP 5mg Net wt of Telmisartan Granules is 10777.600 Kgs. Net wt of Amlodipine Besilate is 400.000 Kgs.) | 1 Number | 4 | Amlodipine Besilate | 5.10 mg |

RA concerned may take further necessary action as per above decision of NC.

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|-------------------------|---------------------------------------------|
| Case No.                | 123 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | BALAJI SPECIALITY CHEMICALS LIMITED         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001636AM23                  |
| RA File Number          | 31AX04000064 AM23                           |
| Licence No and Date     | 3111001476/24/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jan/202122/15 dated 17/03/2022** against advance authorization No. **3111000148 dated 09/02/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                         | Qty. | Sl. No. | Import items       | Qty.                                   |
|----------------------------------------|------|---------|--------------------|----------------------------------------|
| ETHYLENE DI AMINE<br>(ORGANIC PRODUCT) | 1 kg | 1       | MONO ETHANOL AMINE | 1.0374 kg                              |
|                                        |      | 2       | AMMONIA ANHYDROUS  | Not allowed, as it is shown indigenous |

RA concerned may take further necessary action as per above decision of NC.

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|------------------------------|---------------------------------------------|
| Case No.                     | 124 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | MITHILA RASAYAN PRIVATE LIMITED             |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001652AM23                  |
| RA File Number               | 03AX04001866 AM23                           |
| Licence No and Date          | 0311015853/24/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 125 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SHREYANS CHEMICALS                          |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001660AM23                  |
| RA File Number               | 03AX04001924 AM23                           |
| Licence No and Date          | 0311015858/25/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 126 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SMS PHARMACEUTICALS LIMITED                 |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001683AM23                  |
| RA File Number               | 09AX04000288 AM23                           |
| Licence No and Date          | 0911003239/27/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------|---------------------------------------------|
| Case No.                | 127 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Deferred                               |
| Party Name              | STERLING AUXILIARIES PVT LTD                |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001673AM23                  |
| RA File Number          | 03AX04001934 AM23                           |

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|------------------------------|-----------------------|
| Licence No and Date          | 0311015879/27/06/2022 |
| Norms Committee Decision:    |                       |
| Deferred for comments of TE. |                       |

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|------------------------------|---------------------------------------------|
| Case No.                     | 128 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | STERILE INDIA PRIVATE LIMITED               |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001720AM23                  |
| RA File Number               | 33AX04000021 AM23                           |
| Licence No and Date          | 3311000772/28/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                | 129 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                             | Case Approved                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                              | RUBICON RESEARCH PRIVATE LIMITED            |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                 | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                          | HQRNORM APPLY 00001695AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                          | 03AX04001892 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                     | 0311015922/28/06/2022                       |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                               |                                             |
| The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Jan/202223/11 dated 31/10/2022</b> against advance authorization No. <b>0311009414 dated 13/12/2021</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |
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| 2 | Maxigesic cold & flu Hot Drink 1000mg/300mg Sachets (Paracetamol & Ibuprofen Sachets 1000 mg & 300 mg)(No. of Sachets 2,00,000 (Net content of Ibuprofen Lysine Salt IH API 102.60 kg)) | 1 Number | 2 | Ibuprofen Lysine Salt IH | 517.77 mg |
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RA concerned may take further necessary action as per above decision of NC.

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| Case No.                | 130 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | BIOXERA PHARMA PRIVATE LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001697AM23                  |
| RA File Number          | 03AX04001885 AM23                           |
| Licence No and Date     | 0311015929/28/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Apr/202223/1 dated 29/04/2022** against advance authorization No. **0311009297 dated 08/12/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product | Qty. | Sl. No. | Import items           | Qty.     |
|----------------|------|---------|------------------------|----------|
| BENFOTIAMINE   | 1 kg | 1       | THIAMINE HYDROCHLORIDE | 0.922 kg |

RA concerned may take further necessary action as per above decision of NC.

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| Case No.                | 131 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | MAIVA PHARMA PRIVATE LIMITED                |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001702AM23                  |
| RA File Number          | 07AX04000446 AM23                           |
| Licence No and          | 0711004428/28/06/2022                       |

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| Date                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                      |          |         |                                                                                    |                                |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                      |          |         |                                                                                    |                                |
| <p>The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Aug/202223/6 dated 09/09/2022</b> against advance authorization No. <b>0711002764 dated 30/12/2021</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                                                                                                                                                                                                      |          |         |                                                                                    |                                |
| Sl. No.                                                                                                                                                                                                                                                                                                                                                                                                                      | Export product                                                                                                                                                                                       | Qty.     | Sl. No. | Import items                                                                       | Qty.                           |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                            | Furosemide Injection 10mg/mL - 2mL Vial(2mL Vial - filled with 20mg of furosemide as bulk drug mixed in water for injection and filled in 2mL Vial and capped with 13mm chlorobutyle Rubber Stopper) | 1 Number | 1       | V-35 4432/50/GREY Westar? RS SIL 1 (13mm Chlorobutyl R/S V- 35 4432/50 Grey - RFS) | Relevant as per packing policy |
| 2                                                                                                                                                                                                                                                                                                                                                                                                                            | Furosemide Injection 10mg/mL - 4mL Vial(4mL Vial - filled with 40mg of furosemide as bulk drug mixed in water for injection and filled in 4mL Vial and capped with 13mm chlorobutyle Rubber Stopper) | 1 Number | 2       | V-35 4432/50/GREY Westar? RS SIL 1 (13mm Chlorobutyl R/S V- 35 4432/50 Grey - RFS) | Relevant as per packing policy |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                      |          |         |                                                                                    |                                |

|                                                                                                                                                                                                                                                                                                                                                                                                                              |                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                     | 132 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                  | Case Approved                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                   | MAIVA PHARMA PRIVATE LIMITED                |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                               | HQRNORM APPLY 00001703AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                               | 07AX04000445 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                          | 0711004432/28/06/2022                       |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                                    |                                             |
| <p>The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Aug/202223/6 dated 09/09/2022</b> against advance authorization No. <b>0711002764 dated 30/12/2021</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                                             |

| Sl. No. | Export product                                                                                                                                                                                       | Qty.     | Sl. No. | Import items                                                                      | Qty.                           |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|-----------------------------------------------------------------------------------|--------------------------------|
| 1       | Furosemide Injection 10mg/mL - 2mL Vial(2mL Vial - filled with 20mg of furosemide as bulk drug mixed in water for injection and filled in 2mL Vial and capped with 13mm chlorobutyle Rubber Stopper) | 1 Number | 1       | V-35 4432/50/GREY Westar? RS SIL 1 (13mm Chlorobutyl R/S V-35 4432/50 Grey - RFS) | Relevant as per packing policy |
| 2       | Furosemide Injection 10mg/mL - 4mL Vial(4mL Vial - filled with 40mg of furosemide as bulk drug mixed in water for injection and filled in 4mL Vial and capped with 13mm chlorobutyle Rubber Stopper) | 1 Number | 2       | V-35 4432/50/GREY Westar? RS SIL 1 (13mm Chlorobutyl R/S V-35 4432/50 Grey - RFS) | Relevant as per packing policy |
| 3       | Prochlorperazine Edisylate Injection USP 10mg/2mL(2mL Vial - Prochlorperazine Edisylate Injection USP 10mg/2mL and capped with 13mm chlorobutyle Rubber Stopper)                                     | 1 Number | 3       | V-35 4432/50/GREY Westar? RS SIL 1 (13mm Chlorobutyl R/S V-35 4432/50 Grey - RFS) | Relevant as per packing policy |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 133 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | MICRO LABS LIMITED                          |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001705AM23                  |
| RA File Number          | 07AX04000436 AM23                           |
| Licence No and Date     | 0711004457/28/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **5/82-ALC4/2020 dated 09.10.2020** against advance authorization No. **0710116125 dated 17.02.2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product             | Qty. | Sl. No. | Import items           | Qty.       |
|---------|----------------------------|------|---------|------------------------|------------|
| 1       | AMOXICILLIN 125 MG + 80000 |      | 1       | AMOXICILLIN TRIHYDRATE | 1704.42 kg |

|   |                                                                                                                                                                                   |                    |   |                                           |            |
|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|---|-------------------------------------------|------------|
|   | FLUCLOXACILLIN 125 MG / 5 ML<br>ORAL SUSPENSION 100ML<br>BOTTLES(AMOXICILLIN 125 MG +<br>FLUCLOXACILLIN 125 MG / 5 ML<br>ORAL SUSPENSION 100ML BOTTLES<br>BP/EP/USP/IP 400.00 KG) | Bottles            |   |                                           |            |
| 2 | AMOXICILLIN 250 MG +<br>FLUCLOXACILLIN 250 MG<br>CAPSULES(AMOXICILLIN 250 MG +<br>FLUCLOXACILLIN 250 MG<br>CAPSULES BP/EP/USP/IP 3000.00 KG)                                      | 4999960<br>Bottles | 2 | FLUCLOXACILLIN SODIUM BP/<br>EP / USP/ IP | 1615.85 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 134 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | MAIVA PHARMA PRIVATE LIMITED                |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001708AM23                  |
| RA File Number          | 07AX04000458 AM23                           |
| Licence No and Date     | 0711004447/28/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09/09/2022** against advance authorization No. **0711002867 dated 20/01/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export Product                                                                                                                                           | Qty.     | Sl. No. | Import Items                                                                  | Qty.                           |
|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|-------------------------------------------------------------------------------|--------------------------------|
| 1       | Sodium Bicarbonate Injection 84mg/mL -50mL Vial(Sodium Bicarbonate as bulk drug filled in 50mL Vial and capped with 20mm Bromobutyl Grey Rubber Stopper) | 1 Number | 1       | S-127 4432/50/Grey Westar RS SIL 1 (20mm Grey Chlorobutyl Rubber Stopper-RFS) | Relevant as per packing policy |
| 2       | Furosemide Injection 10mg/mL - 10mL Vial(10mL Vial - filled with 100mg of furosemide as bulk drug mixed in water                                         | 1 Number | 2       | S-127 4432/50/Grey Westar RS SIL 1 (20mm Grey                                 | Relevant as per packing policy |

|  |                                                                                           |  |  |                                 |  |
|--|-------------------------------------------------------------------------------------------|--|--|---------------------------------|--|
|  | for injection and filled in 4mL Vial and capped with 20mm Bromobutyl Grey Rubber Stopper) |  |  | Chlorobutyl Rubber Stopper-RFS) |  |
|--|-------------------------------------------------------------------------------------------|--|--|---------------------------------|--|

RA concerned may take further necessary action as per above decision of NC.

| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                          | 135 / NC/3/MEET/Dec/202223/15               |                |                                                                               |                                |              |      |                                                                                                                                                           |          |   |                                                                               |                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------|-------------------------------------------------------------------------------|--------------------------------|--------------|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|-------------------------------------------------------------------------------|--------------------------------|
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                       | Case Approved                               |                |                                                                               |                                |              |      |                                                                                                                                                           |          |   |                                                                               |                                |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                        | MAIVA PHARMA PRIVATE LIMITED                |                |                                                                               |                                |              |      |                                                                                                                                                           |          |   |                                                                               |                                |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                           | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |                                                                               |                                |              |      |                                                                                                                                                           |          |   |                                                                               |                                |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                    | HQRNORM APPLY 00001709AM23                  |                |                                                                               |                                |              |      |                                                                                                                                                           |          |   |                                                                               |                                |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                    | 07AX04000456 AM23                           |                |                                                                               |                                |              |      |                                                                                                                                                           |          |   |                                                                               |                                |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                               | 0711004448/28/06/2022                       |                |                                                                               |                                |              |      |                                                                                                                                                           |          |   |                                                                               |                                |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                                                         |                                             |                |                                                                               |                                |              |      |                                                                                                                                                           |          |   |                                                                               |                                |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Aug/202223/6 dated 09/09/2022</b> against advance authorization No. <b>0711002867 dated 20/01/2022</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:                                       |                                             |                |                                                                               |                                |              |      |                                                                                                                                                           |          |   |                                                                               |                                |
| <table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty.</th></tr><tr><td>Sodium Bicarbonate Injection 84mg/mL - 50mL Vial(Sodium Bicarbonate as bulk drug filled in 50mL Vial and capped with 20mm Bromobutyl Grey Rubber Stopper)</td><td>1 Number</td><td>1</td><td>S-127 4432/50/Grey Westar RS SIL 1 (20mm Grey Chlorobutyl Rubber Stopper-RFS)</td><td>Relevant as per packing policy</td></tr></table> |                                             | Export Product | Qty.                                                                          | Sl. No.                        | Import Items | Qty. | Sodium Bicarbonate Injection 84mg/mL - 50mL Vial(Sodium Bicarbonate as bulk drug filled in 50mL Vial and capped with 20mm Bromobutyl Grey Rubber Stopper) | 1 Number | 1 | S-127 4432/50/Grey Westar RS SIL 1 (20mm Grey Chlorobutyl Rubber Stopper-RFS) | Relevant as per packing policy |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                                                                    | Qty.                                        | Sl. No.        | Import Items                                                                  | Qty.                           |              |      |                                                                                                                                                           |          |   |                                                                               |                                |
| Sodium Bicarbonate Injection 84mg/mL - 50mL Vial(Sodium Bicarbonate as bulk drug filled in 50mL Vial and capped with 20mm Bromobutyl Grey Rubber Stopper)                                                                                                                                                                                                                                                                                         | 1 Number                                    | 1              | S-127 4432/50/Grey Westar RS SIL 1 (20mm Grey Chlorobutyl Rubber Stopper-RFS) | Relevant as per packing policy |              |      |                                                                                                                                                           |          |   |                                                                               |                                |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                                                       |                                             |                |                                                                               |                                |              |      |                                                                                                                                                           |          |   |                                                                               |                                |

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 136 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | AARTI DRUGS LIMITED                         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001737AM23                  |
| RA File Number          | 03AX04001906 AM23                           |
| Licence No and          | 0311015967/29/06/2022                       |

|                                                                                                                                                                                                                                                                                                                                                                                                                    |      |         |                                                                  |          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---------|------------------------------------------------------------------|----------|
| Date                                                                                                                                                                                                                                                                                                                                                                                                               |      |         |                                                                  |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                          |      |         |                                                                  |          |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Nov/202223/12 dated 18/11/2022</b> against advance authorization No. <b>0311013055 dated 17/03/2022</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |      |         |                                                                  |          |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                     | Qty. | Sl. No. | Import items                                                     | Qty.     |
| Ciprofloxacin Hydrochloride IP                                                                                                                                                                                                                                                                                                                                                                                     | 1 kg | 1       | Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate | 1.240 kg |
|                                                                                                                                                                                                                                                                                                                                                                                                                    |      | 2       | Piperazine Anhydrous                                             | 0.390 kg |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                        |      |         |                                                                  |          |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 137 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | ALCHEMIE FINECHEM PRIVATE LIMITED           |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001739AM23                  |
| RA File Number               | 03AX04001857 AM23                           |
| Licence No and Date          | 0311015970/29/06/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                           |                                             |
|---------------------------|---------------------------------------------|
| Case No.                  | 138 / NC/3/MEET/Dec/202223/15               |
| Case Status               | Case Deferred                               |
| Party Name                | BEST VALUE CHEM PRIVATE LIMITED             |
| Meeting Number and Date   | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number            | HQRNORM APPLY 00001745AM23                  |
| RA File Number            | 34AX04000259 AM23                           |
| Licence No and Date       | 3411002449/29/06/2022                       |
| Norms Committee Decision: |                                             |

The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:

- i. Complete calculation for the requirement of Magnesium Turning in the process.
- ii. Yield of the reaction giving justification of wastage of Magnesium Turning.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 139 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | FDC LIMITED                                 |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001755AM23                  |
| RA File Number          | 03AX04001963 AM23                           |
| Licence No and Date     | 0311015976/29/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Apr/202223/1 dated 29/04/2022** against advance authorization No. **0311009325 dated 09-12-2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                                                            | Qty.     | Sl. No. | Import items               | Qty.            |
|---------------------------------------------------------------------------------------------------------------------------|----------|---------|----------------------------|-----------------|
| CHLORAMPHENICOL EYE DROPS 10 ML((EACH VIAL CONTAINS CHLORAMPHENICOL MICRONIZED 0.050GM NET WT OF BULK DRUG IS 25.20 KGS)) | 1 Number | 1       | Chloramphenicol Micronized | 51.00 mg / Vial |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 140 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | THINQ PHARMA-CRO LIMITED                    |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001778AM23                  |
| RA File Number          | 03AX04001927 AM23                           |
| Licence No and          | 0311016002/30/06/2022                       |

|                                                                                                                                                                                                                                                                                                                                                                                                                    |      |         |                                     |          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---------|-------------------------------------|----------|
| Date                                                                                                                                                                                                                                                                                                                                                                                                               |      |         |                                     |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                          |      |         |                                     |          |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Oct/202223/11 dated 31/10/2022</b> against advance authorization No. <b>0310833909 dated 06-01-2020</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |      |         |                                     |          |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                     | Qty. | Sl. No. | Import items                        | Qty.     |
| G-101 (ALL TRANS RETINOIC ACID, 1-HYDROXY-3, 3-DIMETHYL-2-BUTANONE ESTER)(NA)                                                                                                                                                                                                                                                                                                                                      | 1 kg | 1       | Tretinoin (All Trans Retinoic Acid) | 1.00 kg  |
|                                                                                                                                                                                                                                                                                                                                                                                                                    |      | 2       | 1-Chloropinacolone                  | 0.600 kg |
|                                                                                                                                                                                                                                                                                                                                                                                                                    |      | 3       | Cesium Carbonate                    | 1.135 kg |
| <p>RA concerned may take further necessary action as per above decision of NC.</p>                                                                                                                                                                                                                                                                                                                                 |      |         |                                     |          |

|                                                                                                                                                                                                                                                                                                                                                                                                                   |                                             |         |                                        |          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------|----------------------------------------|----------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                          | 141 / NC/3/MEET/Dec/202223/15               |         |                                        |          |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                       | Case Approved                               |         |                                        |          |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                        | DIAMINES AND CHEMICALS LIMITED              |         |                                        |          |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                           | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |         |                                        |          |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                    | HQRNORM APPLY 00001780AM23                  |         |                                        |          |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                    | 34AX04000307 AM23                           |         |                                        |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                               | 3411002467/30/06/2022                       |         |                                        |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                         |                                             |         |                                        |          |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Sep/202223/9 dated 07/10/2022</b> against advance authorization No. <b>3411000643 dated 27-05-2021</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                                             |         |                                        |          |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                                    | Qty                                         | Sl. No. | Import Item Name.                      | Qty.     |
| PIPERAZINE ANHYDROUS                                                                                                                                                                                                                                                                                                                                                                                              | 1 kg                                        | 1       | PIPERAZINE CRUDE OR PIPERAZINE MIXTURE | 2.047 kg |

|  |  |  |                               |  |
|--|--|--|-------------------------------|--|
|  |  |  | (Percentage purity NMT 48.1%) |  |
|--|--|--|-------------------------------|--|

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 142 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | SYSCEM (INDIA) LIMITED                      |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001784AM23                  |
| RA File Number          | 30AX04000118 AM23                           |
| Licence No and Date     | 3011002330/30/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export Product         | Qty  | Sl. No. | Import Item Name.                         | Qty.      |
|------------------------|------|---------|-------------------------------------------|-----------|
| Amoxycillin Trihydrate | 1 kg | 1       | 6APA                                      | 0.568 kg  |
|                        |      | 2       | D-(-)-4-HYDROXYPHENYLGLYCINE METHYL ESTER | 0.4816 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 143 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | DEEPAK PHENOLICS LIMITED                    |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001786AM23                  |
| RA File Number          | 34AX04000287 AM23                           |
| Licence No and Date     | 3411002469/30/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **3411002081 dated 31/03/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product | Qty. | Sl. No. | Import items | Qty.       |
|----------------|------|---------|--------------|------------|
| Phenol         | 1 MT | 1       | Cumene       | 0.84466 MT |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 144 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | VN CREATIVE CHEMICALS PRIVATE LIMITED       |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001767AM23                  |
| RA File Number          | 03AX04001960 AM23                           |
| Licence No and Date     | 0311015992/30/06/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/14 dated 07/12/2022** against advance authorization No. **0310824780 dated 29/10/2018**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export Product | Qty  | Sl. No. | Import Items                     | Qty      |
|----------------|------|---------|----------------------------------|----------|
| Tonalid        | 1 kg | 1       | D M B-1 (2, 3 Dimethyl 1 Butene) | 0.896 kg |
|                |      | 2       | Paracymene                       | 0.750 kg |

RA concerned may take further necessary action as per above decision of NC.

|          |                               |
|----------|-------------------------------|
| Case No. | 145 / NC/3/MEET/Dec/202223/15 |
|----------|-------------------------------|

| Case Status                                                                                                                                                                                                                                                                                                                                                                                               | Case Approved                               |         |                   |           |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------|-------------------|-----------|----------------|------|---------|--------------|------|--------------------------------------------------|------|---|-------------------|----------|---|-----------------|-----------|
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                | STERILE INDIA PRIVATE LIMITED               |         |                   |           |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                   | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |         |                   |           |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                            | HQRNORM APPLY 00001772AM23                  |         |                   |           |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                            | 05AX04000929 AM23                           |         |                   |           |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                       | 0511013506/30/06/2022                       |         |                   |           |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                 |                                             |         |                   |           |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>7/82-ALC4/2020 dated 04/12/2020</b> against advance authorization No. <b>0510414761 dated 28-07-2020</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                                             |         |                   |           |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |
| <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Piperacillin and Tazobactam Sodium Sterile (8:1)</td> <td rowspan="2">1 kg</td> <td>1</td> <td>PIPERACILLIN ACID</td> <td>0.890 kg</td> </tr> <tr> <td>2</td> <td>TAZOBACTAM ACID</td> <td>0.1078 kg</td> </tr> </tbody> </table>  |                                             |         |                   |           | Export Product | Qty. | Sl. No. | Import items | Qty. | Piperacillin and Tazobactam Sodium Sterile (8:1) | 1 kg | 1 | PIPERACILLIN ACID | 0.890 kg | 2 | TAZOBACTAM ACID | 0.1078 kg |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                            | Qty.                                        | Sl. No. | Import items      | Qty.      |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |
| Piperacillin and Tazobactam Sodium Sterile (8:1)                                                                                                                                                                                                                                                                                                                                                          | 1 kg                                        | 1       | PIPERACILLIN ACID | 0.890 kg  |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |
|                                                                                                                                                                                                                                                                                                                                                                                                           |                                             | 2       | TAZOBACTAM ACID   | 0.1078 kg |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                               |                                             |         |                   |           |                |      |         |              |      |                                                  |      |   |                   |          |   |                 |           |

|                              |                                             |  |  |  |
|------------------------------|---------------------------------------------|--|--|--|
| Case No.                     | 146 / NC/3/MEET/Dec/202223/15               |  |  |  |
| Case Status                  | Case Deferred                               |  |  |  |
| Party Name                   | JUBILANT INGREVIA LIMITED                   |  |  |  |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |  |  |  |
| HQ File Number               | HQRNORM APPLY 00001773AM23                  |  |  |  |
| RA File Number               | 05AX04000689 AM23                           |  |  |  |
| Licence No and Date          | 0511013507/30/06/2022                       |  |  |  |
| Norms Committee Decision:    |                                             |  |  |  |
| Deferred for comments of TE. |                                             |  |  |  |

|                         |                                             |  |  |  |
|-------------------------|---------------------------------------------|--|--|--|
| Case No.                | 147 / NC/3/MEET/Dec/202223/15               |  |  |  |
| Case Status             | Case Approved                               |  |  |  |
| Party Name              | BEST VALUE CHEM PRIVATE LIMITED             |  |  |  |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |  |  |  |
| HQ File Number          | HQRNORM APPLY 00001795AM23                  |  |  |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                   |                       |         |                                                  |          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------|--------------------------------------------------|----------|
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                    | 34AX04000311 AM23     |         |                                                  |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                               | 3411002472/01/07/2022 |         |                                                  |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                         |                       |         |                                                  |          |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Jun/202122/2 dated 02/07/2021</b> against advance authorization No. <b>3411000623 dated 25-05-2021</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                       |         |                                                  |          |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                                    | Qty.                  | Sl. No. | Import items                                     | Qty.     |
| MELONAL (2,6-dimethylhept-5-enal)<br>(Clear colorless liquid)                                                                                                                                                                                                                                                                                                                                                     | 1 kg                  | 1       | Methyl Heptenone                                 | 1.125 kg |
|                                                                                                                                                                                                                                                                                                                                                                                                                   |                       | 2       | Methyl Mono Chloro Acetate/ Ethyl Chloro Acetate | 1.201 kg |
|                                                                                                                                                                                                                                                                                                                                                                                                                   |                       | 3       | Sodium Methoxide                                 | 0.562 kg |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                       |                       |         |                                                  |          |

|                                                                                                                                                                                                        |                                             |          |         |                      |                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------|---------|----------------------|-----------------|
| Case No.                                                                                                                                                                                               | 148 / NC/3/MEET/Dec/202223/15               |          |         |                      |                 |
| Case Status                                                                                                                                                                                            | Case Approved                               |          |         |                      |                 |
| Party Name                                                                                                                                                                                             | MAIVA PHARMA PRIVATE LIMITED                |          |         |                      |                 |
| Meeting Number and Date                                                                                                                                                                                | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |          |         |                      |                 |
| HQ File Number                                                                                                                                                                                         | HQRNORM APPLY 00001804AM23                  |          |         |                      |                 |
| RA File Number                                                                                                                                                                                         | 07AX04000482 AM23                           |          |         |                      |                 |
| Licence No and Date                                                                                                                                                                                    | 0711004485/01/07/2022                       |          |         |                      |                 |
| Norms Committee Decision:                                                                                                                                                                              |                                             |          |         |                      |                 |
| <p>The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                                             |          |         |                      |                 |
| Sl. No.                                                                                                                                                                                                | Export Product                              | Qty.     | Sl. No. | Import items         | Qty.            |
| 1                                                                                                                                                                                                      | Bumetanide Injection 0.25mg/mL, 4mL         | 1 Number | 1       | V-35 4031/45G DC SIL | Relevant as per |

|   |                                                                                                          |          |   |                                                                                       |                                |
|---|----------------------------------------------------------------------------------------------------------|----------|---|---------------------------------------------------------------------------------------|--------------------------------|
|   | vial(Bumetanide Injection 0.25mg/mL, 4mL vial)                                                           |          |   | WesterSELECT RS P02(13mm Serum Non laminated Bromobutyl R/S RFS)                      | packing policy                 |
| 2 | Bumetanide Injection 0.25mg/mL, 10mL vial(Bumetanide Injection 0.25mg/mL, 10mL vial)                     | 1 Number | 2 | V-35 4031/45G DC SIL WesterSELECT RS P02(13mm Serum Non laminated Bromobutyl R/S RFS) | Relevant as per packing policy |
| 3 | Famotidine Injection 10mg/mL, 2mL vial(Famotidine Injection 10mg/mL, 2mL vial)                           | 1 Number | 3 | V-35 4031/45G DC SIL WesterSELECT RS P02(13mm Serum Non laminated Bromobutyl R/S RFS) | Relevant as per packing policy |
| 4 | Diltiazem Hydrochloride Injection 5mg/mL, 5mL vial(Diltiazem Hydrochloride Injection 5mg/mL, 5mL vial)   | 1 Number | 4 | S-127 4031/45G DCSIL WesterSELECT RS P02(20mm Serum Non laminated Bromobutyl R/S RFS) | Relevant as per packing policy |
| 5 | Diltiazem Hydrochloride Injection 5mg/mL, 10mL vial(Diltiazem Hydrochloride Injection 5mg/mL, 10mL vial) | 1 Number | 5 | S-127 4031/45G DCSIL WesterSELECT RS P02(20mm Serum Non laminated Bromobutyl R/S RFS) | Relevant as per packing policy |
| 6 | Diltiazem Hydrochloride Injection 5mg/mL, 25mL vial(Diltiazem Hydrochloride Injection 5mg/mL, 25mL vial) | 1 Number | 6 | S-127 4031/45G DCSIL WesterSELECT RS P02(20mm Serum Non laminated Bromobutyl R/S RFS) | Relevant as per packing policy |

RA concerned may take further necessary action as per above decision of NC.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 149 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | YASHO INDUSTRIES LIMITED                    |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001814AM23                  |
| RA File Number               | 03AX04002032 AM23                           |
| Licence No and Date          | 0311016038/03/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|             |                               |
|-------------|-------------------------------|
| Case No.    | 150 / NC/3/MEET/Dec/202223/15 |
| Case Status | Case Deferred                 |
| Party Name  | YASHO INDUSTRIES LIMITED      |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001815AM23                  |
| RA File Number               | 03AX04002034 AM23                           |
| Licence No and Date          | 0311016039/03/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                                                                                                                                                                       |                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                                                                                                                              | 151 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                           | Case Deferred                               |
| Party Name                                                                                                                                                            | ENCUBE ETHICALS PRIVATE LIMITED             |
| Meeting Number and Date                                                                                                                                               | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                        | HQRNORM APPLY 00001817AM23                  |
| RA File Number                                                                                                                                                        | 03AX04001952 AM23                           |
| Licence No and Date                                                                                                                                                   | 0311016049/04/07/2022                       |
| Norms Committee Decision:                                                                                                                                             |                                             |
| The Committee considered the case as per agenda and it was decided to call the firm for attending <b>Personal Hearing</b> before Norms Committee to explain its case. |                                             |

|                                                                                                                                                                                                                                                                                                                                                                                                             |                                             |                |                   |          |              |      |            |      |   |                   |          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------|-------------------|----------|--------------|------|------------|------|---|-------------------|----------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                    | 152 / NC/3/MEET/Dec/202223/15               |                |                   |          |              |      |            |      |   |                   |          |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                 | Case Approved                               |                |                   |          |              |      |            |      |   |                   |          |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                  | BALAJI AMINES LIMITED                       |                |                   |          |              |      |            |      |   |                   |          |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                     | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |                   |          |              |      |            |      |   |                   |          |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                              | HQRNORM APPLY 00001842AM23                  |                |                   |          |              |      |            |      |   |                   |          |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                              | 31AX04000093 AM23                           |                |                   |          |              |      |            |      |   |                   |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                         | 3111001507/04/07/2022                       |                |                   |          |              |      |            |      |   |                   |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                   |                                             |                |                   |          |              |      |            |      |   |                   |          |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Sep/202223/8 dated 23/09/2022</b> against advance authorization No. <b>3111000445 dated 08/07/2021</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |                |                   |          |              |      |            |      |   |                   |          |
| <table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>MORPHOLINE</td><td>1 kg</td><td>1</td><td>DIETHYLENE GLYCOL</td><td>1.279 kg</td></tr></table>                                                                                                                                                                                                |                                             | Export Product | Qty.              | Sl. No.  | Import items | Qty. | MORPHOLINE | 1 kg | 1 | DIETHYLENE GLYCOL | 1.279 kg |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                              | Qty.                                        | Sl. No.        | Import items      | Qty.     |              |      |            |      |   |                   |          |
| MORPHOLINE                                                                                                                                                                                                                                                                                                                                                                                                  | 1 kg                                        | 1              | DIETHYLENE GLYCOL | 1.279 kg |              |      |            |      |   |                   |          |

|  |  |   |                     |                                              |
|--|--|---|---------------------|----------------------------------------------|
|  |  | 2 | AMMONIA ANHYDROUS   | 0.217 kg                                     |
|  |  | 3 | HYDROGEN            | Not allowed, as it is procured indigenously. |
|  |  | 4 | MORPHOLINE CATALYST | Not allowed as no catalogue is available.    |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                                   |
|-------------------------|---------------------------------------------------|
| Case No.                | 153 / NC/3/MEET/Dec/202223/15                     |
| Case Status             | Case Approved                                     |
| Party Name              | BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022       |
| HQ File Number          | HQRNORM APPLY 00001818AM23                        |
| RA File Number          | 03AX04001996 AM23                                 |
| Licence No and Date     | 0311016051/04/07/2022                             |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export Product                                                                         | Qty.   | Sl. No. | Import items        | Qty.         |
|---------|----------------------------------------------------------------------------------------|--------|---------|---------------------|--------------|
| 1       | CASPOFUNGIN ACETATE FOR INJECTION 50MG. ( Net content of CASPOFUNGIN ACETATE 2.50 kgs  | 1 Vial | 1       | CASPOFUNGIN ACETATE | 55 mg / Vial |
| 2       | CASPOFUNGIN ACETATE FOR INJECTION 70MG. ( Net content of CASPOFUNGIN ACETATE 1.400 kgs | 1 Vial | 2       | CASPOFUNGIN ACETATE | 77 mg / Vial |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 154 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | GLENMARK PHARMACEUTICALS LIMITED            |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001819AM23                  |
| RA File Number          | 03AX04001989 AM23                           |
| Licence No and Date     | 0311016055/04/07/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/May/202223/3 dated 27/05/2022** against advance authorization No. **0311006129 dated 13/08/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export Product                                                                                                                                                                                                   | Qty.           | Sl. No. | Import Items                | Qty.       |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|---------|-----------------------------|------------|
| 1       | Momate AZ NASAL SPRAY 150 MD /Mometasone Furoate & Azelastine HCL Nasal Spray (150MD)((Net Wt. of Azelastine Hydrochloride BP 5250 Grams))                                                                       | 250000 Numbers | 1       | Azelastine Hydrochloride BP | 5355 grams |
| 2       | Furoate & Azelastine Hydrochloride Nasal Spray (75MD)(Momat Rino Advance 75 MD/MOMATE AZ NASAL SPRAY 75 MD/(GLENSPRAY ACTIVE 75 NS Pack size : 75 MD bottle (Net Wt. of Azelastine Hydrochloride BP 2100 Grams)) | 200000 Numbers | 2       | Azelastine Hydrochloride BP | 2142 grams |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 155 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | BALAJI SPECIALITY CHEMICALS LIMITED         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001824AM23                  |
| RA File Number          | 31AX04000054 AM23                           |
| Licence No and Date     | 3111001493/04/07/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Mar/202122/15 dated 17/03/2022** against advance authorization No. **3111000148 dated 09/02/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                         | Qty. | Sl. No. | Import items       | Qty.                                   |
|----------------------------------------|------|---------|--------------------|----------------------------------------|
| ETHYLENE DI AMINE<br>(ORGANIC CHEMICAL | 1 kg | 1       | MONO ETHANOL AMINE | 1.0374 kg                              |
|                                        |      | 2       | AMMONIA ANHYDROUS  | Not allowed, as it is shown indigenous |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 156 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | IPCA LABORATORIES LIMITED                   |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001828AM23                  |
| RA File Number          | 03AX04001961 AM23                           |
| Licence No and Date     | 0311016065/04/07/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/14 dated 07/12/2022** against advance authorization No. **0311006518 dated 28/08/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product | Qty. | Sl. No. | Import items       | Qty.     |
|----------------|------|---------|--------------------|----------|
| FRUSEMIDE      | 1 kg | 1       | LASAMIDE           | 0.910 kg |
|                |      | 2       | FURFURYLAMINE      | 1.207 kg |
|                |      | 3       | ISO PROPYL ALCOHOL | 1.00 kg  |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 157 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | J B CHEMICALS AND PHARMACEUTICALS LIMITED   |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001829AM23                  |
| RA File Number          | 03AX04001031 AM23                           |
| Licence No and Date     | 0311016066/04/07/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/9 dated 07.10.2022** against advance authorization No. **0311012326 dated 07.03.2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                                                                                                                                                                                                                                                                  | Qty.            | Sl. No. | Import items              | Qty.                    |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------|---------------------------|-------------------------|
| 1       | Rinza sip with Vitamin C (Flavours Orange/ Lemon/ Black Currant/ Other flavours) &(Rinza Sip (Flavours Orange/ Lemon/ Black currant/ Cranberry/ Honey Lemon/ Other flavours). Each sachet of 5gm contains Caffeine Anhydrous Powder 30mg. Net content of Caffeine Anhydrous Powder 923.64 Kgs.) | 1 Number Sachet | 1       | Caffeine Anhydrous Powder | 30.30 mg / 5 gm sachet  |
| 2       | Rinza Tablets. Each tablet Contains Caffeine Anhydrous Powder 30 mg and Paracetamol BP 500 mg.(Net Content of Caffeine Anhydrous Powder - 960 Kgs and Paracetamol BP - 16000 Kgs.)                                                                                                              | 1 Number Tablet | 2       | Caffeine Anhydrous Powder | 30.60 mg / 30 mg tablet |
|         |                                                                                                                                                                                                                                                                                                 |                 | 3       | Paracetamol BP            | 510 mg / 500 mg tablet  |
| 3       | Rinza Sip for Children (Flavours Raspberry/ other flavours). Each sachet of 3gm contains Paracetamol BP - 280mg.(Net content- 576.92 Kgs.)                                                                                                                                                      | 1 Number Sachet | 4       | Paracetamol BP            | 282.80 mg / 3 gm sachet |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 158 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | STERILE INDIA PRIVATE LIMITED               |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001835AM23                  |
| RA File Number          | 05AX04000925 AM23                           |
| Licence No and Date     | 0511013563/04/07/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/May/202223/4 dated 17.06.2022** against advance authorization No. **0510412070 dated 10.10.2019**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                | Qty. | Sl. No. | Import items                               | Qty.    |
|-------------------------------|------|---------|--------------------------------------------|---------|
| Deferoxamine Mesylate Sterile | 1 kg | 1       | Deferoxamine Mesylate USP<br>(Non-Sterile) | 1.02 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 159 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Deferred                               |
| Party Name              | ENCUBE ETHICALS PRIVATE LIMITED             |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001837AM23                  |
| RA File Number          | 03AX04001983 AM23                           |
| Licence No and Date     | 0311016079/04/07/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to call the firm for attending **Personal Hearing** before Norms Committee to explain its case.

|          |                               |
|----------|-------------------------------|
| Case No. | 160 / NC/3/MEET/Dec/202223/15 |
|----------|-------------------------------|

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case Status                  | Case Deferred                               |
| Party Name                   | SAGA LIFESCIENCES LIMITED                   |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001849AM23                  |
| RA File Number               | 08AX04000569 AM23                           |
| Licence No and Date          | 0811005433/05/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 161 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | ALEMBIC PHARMACEUTICALS LIMITED             |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001862AM23                  |
| RA File Number          | 34AX04000323 AM23                           |
| Licence No and Date     | 3411002491/05/07/2022                       |

## Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/14** dated **07.12.2022** against advance authorization No. **3411001604** dated **29.12.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                                                                               | Qty.     | Sl. No. | Import items                                 | Qty.     |
|---------|--------------------------------------------------------------------------------------------------------------|----------|---------|----------------------------------------------|----------|
| 1       | Duloxetine Caps.20 mg<br>(Duloxetine Caps.20 mg Capsule<br>(Net content of active ingredients 50.000 kgs ) ) | 1 Number | 1       | Duloxetine Hydrochloride Ph,Eur.             | 22.88 mg |
|         |                                                                                                              |          | 2       | Sugar Spheres (30-35 PHARM-A-SPHERES)        | 20.33 mg |
|         |                                                                                                              |          | 3       | Hypromellose (Pharmacoat 606)                | 20.00 mg |
|         |                                                                                                              |          | 4       | Talc (Luzenac Pharma Ultra Micronised grade) | 12.63 mg |
|         |                                                                                                              |          | 5       | Sucrose (Compressuc PS)                      | 15.67 mg |

|   |                                                                                                  |                  |   |                                              |          |
|---|--------------------------------------------------------------------------------------------------|------------------|---|----------------------------------------------|----------|
|   |                                                                                                  |                  | 6 | Hypromellose Phthalate (HP 55)               | 12.07 mg |
|   |                                                                                                  |                  | 7 | Triethyl Citrate                             | 1.21 mg  |
| 2 | Duloxetine Caps. 30 mg (Duloxetine Caps. 30 mg (Net content of active ingredients 135.00 kgs ) ) | 1 Number Capsule | 1 | Duloxetine Hydrochloride Ph,Eur.             | 34.36 mg |
|   |                                                                                                  |                  | 2 | Sugar Spheres (30-35 PHARM-A-SPHERES)        | 30.50 mg |
|   |                                                                                                  |                  | 3 | Hypromellose (Pharmacoat 606)                | 30.00 mg |
|   |                                                                                                  |                  | 4 | Talc (Luzenac Pharma Ultra Micronised grade) | 18.94 mg |
|   |                                                                                                  |                  | 5 | Sucrose (Compressuc PS)                      | 23.50 mg |
|   |                                                                                                  |                  | 6 | Hypromellose Phthalate (HP 55)               | 18.10 mg |
|   |                                                                                                  |                  | 7 | Triethyl Citrate                             | 1.81 mg  |
| 3 | Duloxetine Caps. 40 mg (Duloxetine Caps. 40 mg (Net content of active ingredients 80.000 kgs ) ) | 1 Number Capsule | 1 | Duloxetine Hydrochloride Ph,Eur.             | 45.76 mg |
|   |                                                                                                  |                  | 2 | Sugar Spheres (30-35 PHARM-A-SPHERES)        | 40.67 mg |
|   |                                                                                                  |                  | 3 | Hypromellose (Pharmacoat 606)                | 40.00 mg |
|   |                                                                                                  |                  | 4 | Talc (Luzenac Pharma Ultra Micronised grade) | 25.26 mg |
|   |                                                                                                  |                  | 5 | Sucrose (Compressuc PS)                      | 31.34 mg |
|   |                                                                                                  |                  | 6 | Hypromellose Phthalate (HP 55)               | 24.14 mg |
|   |                                                                                                  |                  | 7 | Triethyl Citrate                             | 2.41 mg  |
| 4 | Duloxetine Caps. 60 mg (Duloxetine Caps. 60 mg (Net content of active                            | 1 Number Capsule | 1 | Duloxetine Hydrochloride Ph,Eur.             | 68.71 mg |
|   |                                                                                                  |                  | 2 | Sugar Spheres (30-35 PHARM-A-                | 61.00 mg |

|  |                           |  |   |                                              |          |
|--|---------------------------|--|---|----------------------------------------------|----------|
|  | ingredients 300.00 kgs )) |  |   | SPHERES)                                     |          |
|  |                           |  | 3 | Hypromellose (Pharmacoat 606)                | 60.00 mg |
|  |                           |  | 4 | Talc (Luzenac Pharma Ultra Micronised grade) | 37.88 mg |
|  |                           |  | 5 | Sucrose (Compressuc PS)                      | 47.00 mg |
|  |                           |  | 6 | Hypromellose Phthalate (HP 55)               | 36.20 mg |
|  |                           |  | 7 | Triethyl Citrate                             | 3.62 mg  |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 162 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | ZIM LABORATORIES LIMITED.                   |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001885AM23                  |
| RA File Number          | 50AX04000031 AM23                           |
| Licence No and Date     | 5011000520/06/07/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jan/202223/4 dated 12.02.2021** against advance authorization No. **0310836218 dated 15.05.2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product           | Qty.   | Sl. No. | Import items                 | Qty.      |
|--------------------------|--------|---------|------------------------------|-----------|
| Acitretin Pellets 10.87% | 259 kg | 1       | Acitretin Micronized Ph. Eur | 28.435 kg |

RA concerned may take further necessary action as per above decision of NC.

| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 163 / NC/3/MEET/Dec/202223/15               |                |              |            |              |      |        |      |   |        |            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------|--------------|------------|--------------|------|--------|------|---|--------|------------|
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Case Approved                               |                |              |            |              |      |        |      |   |        |            |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | DEEPAK PHENOLICS LIMITED                    |                |              |            |              |      |        |      |   |        |            |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |              |            |              |      |        |      |   |        |            |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | HQRNORM APPLY 00001889AM23                  |                |              |            |              |      |        |      |   |        |            |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 34AX04000335 AM23                           |                |              |            |              |      |        |      |   |        |            |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 3411002501/06/07/2022                       |                |              |            |              |      |        |      |   |        |            |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Nov/202223/12 dated 18/11/2022</b> against advance authorization No. <b>3411002081 dated 31/03/2022</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> <table border="1"> <thead> <tr> <th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> <tr> <td>Phenol</td><td>1 MT</td><td>1</td><td>Cumene</td><td>0.84466 MT</td></tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision of NC.</p> |                                             | Export product | Qty.         | Sl. No.    | Import items | Qty. | Phenol | 1 MT | 1 | Cumene | 0.84466 MT |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Qty.                                        | Sl. No.        | Import items | Qty.       |              |      |        |      |   |        |            |
| Phenol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 1 MT                                        | 1              | Cumene       | 0.84466 MT |              |      |        |      |   |        |            |

| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 164 / NC/3/MEET/Dec/202223/15               |                |              |         |              |      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------|--------------|---------|--------------|------|
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Case Approved                               |                |              |         |              |      |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | FINE ORGANIC INDUSTRIES LIMITED             |                |              |         |              |      |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |              |         |              |      |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | HQRNORM APPLY 00001874AM23                  |                |              |         |              |      |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 03AX04002054 AM23                           |                |              |         |              |      |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 0311016128/06/07/2022                       |                |              |         |              |      |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>10/82-ALC4/2018 dated 16.10.2018</b> against advance authorization No. <b>0310821155 dated 22.05.2018</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> <table border="1"> <thead> <tr> <th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> </tbody> </table> |                                             | Export product | Qty.         | Sl. No. | Import items | Qty. |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Qty.                                        | Sl. No.        | Import items | Qty.    |              |      |

|                   |      |   |               |          |
|-------------------|------|---|---------------|----------|
| STEARYL ERUCAMIDE | 1 kg | 1 | ERUCIC ACID   | 0.592 kg |
|                   |      | 2 | STEARYL AMINE | 0.471 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 165 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | MAIVA PHARMA PRIVATE LIMITED                |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001876AM23                  |
| RA File Number          | 07AX04000490 AM23                           |
| Licence No and Date     | 0711004564/06/07/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09/09/2022** against advance authorization No. **0711002867 dated 20/01/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export Product                                                                                                                                           | Qty.     | Sl. No. | Import Items                                     | Qty.                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|--------------------------------------------------|--------------------------------|
| Sodium Bicarbonate Injection 84mg/mL -50mL Vial(Sodium Bicarbonate as bulk drug filled in 50mL Vial and capped with 20mm Bromobutyl Grey Rubber Stopper) | 1 Number | 1       | 50 mL / 20mm neck Serum Type I CLR, Molded Vials | Relevant as per packing policy |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 166 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | ALEMBIC PHARMACEUTICALS LIMITED             |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001878AM23                  |

|                     |                       |
|---------------------|-----------------------|
| RA File Number      | 34AX04000325 AM23     |
| Licence No and Date | 3411002498/06/07/2022 |

## Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/14** dated **07/12/2022** against advance authorization No. **3411001662** dated **07/01/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                                                                                                                            | Qty.             | Sl. No. | Import items                                                       | Qty.      |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------|--------------------------------------------------------------------|-----------|
| 1       | Amantadine Hydrochloride capsules USP 100mg (Amantadine Hydrochloride capsules USP 100mg (Net content of active ingredients 420.00 kgs )) | 1 Number Capsule | 1       | Amantadine Hydrochloride USP                                       | 102.00 mg |
|         |                                                                                                                                           |                  | 2       | Microcrystalline cellulose (Avicel PH301)                          | 106.00 mg |
|         |                                                                                                                                           |                  | 3       | Hydroxypropyl Cellulose (Klucel LF)                                | 2.00 mg   |
|         |                                                                                                                                           |                  | 4       | Croscarmellose Sodium (Ac-Di-Sol)                                  | 10.00 mg  |
|         |                                                                                                                                           |                  | 5       | Colloidal Silicon Dioxide (Aerosil 200 Pharma)                     | 1.00 mg   |
|         |                                                                                                                                           |                  | 6       | Magnesium Stearate (Vegetable Source)                              | 1.00 mg   |
| 2       | Amantadine Hydrochloride Tablets USP 100mg (Amantadine Hydrochloride Tablets USP 100mg (Net content of active ingredients 520.00 kgs ))   | 1 Number Tablet  | 1       | Amantadine Hydrochloride USP                                       | 102.00 mg |
|         |                                                                                                                                           |                  | 2       | Microcrystalline Cellulose (Avicel PH 101)                         | 33.65 mg  |
|         |                                                                                                                                           |                  | 3       | Povidone (Kollidon 90F)                                            | 3.00 mg   |
|         |                                                                                                                                           |                  | 4       | Lake Pigment HT 5285 FD&C Yellow 6 Sunset Yellow FCF Aluminum Lake | 0.300 mg  |
|         |                                                                                                                                           |                  | 5       | Sodium Starch Glycolate (Type A) (EXPLOTAB)                        | 4.50 mg   |
|         |                                                                                                                                           |                  | 6       | Povidone (K-30)                                                    | 3.00 mg   |
|         |                                                                                                                                           |                  | 7       | Colloidal Silicon Dioxide (Aerosil 200 Pharma)                     | 0.75 mg   |

|                                                                             |  |  |   |                    |         |
|-----------------------------------------------------------------------------|--|--|---|--------------------|---------|
|                                                                             |  |  | 8 | Magnesium Stearate | 0.80 mg |
| RA concerned may take further necessary action as per above decision of NC. |  |  |   |                    |         |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 167 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | OPTIMUS DRUGS PRIVATE LIMITED               |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001879AM23                  |
| RA File Number               | 09AX04000318 AM23                           |
| Licence No and Date          | 0911003277/06/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 168 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | OPTIMUS DRUGS PRIVATE LIMITED               |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001881AM23                  |
| RA File Number               | 09AX04000311 AM23                           |
| Licence No and Date          | 0911003280/06/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 169 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | OPTIMUS DRUGS PRIVATE LIMITED               |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001892AM23                  |
| RA File Number               | 09AX04000308 AM23                           |
| Licence No and Date          | 0911003285/07/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 170 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SHREE GANESH REMEDIES LIMITED               |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001895AM23                  |
| RA File Number               | 34AX04000273 AM23                           |
| Licence No and Date          | 3411002508/07/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 171 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | HONOUR LAB LIMITED                          |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001896AM23                  |
| RA File Number          | 09AX04000262 AM23                           |
| Licence No and Date     | 0911003287/07/07/2022                       |

## Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0911002884 dated 21/04/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                           | Qty. | Sl. No. | Import items                        | Qty.     |
|------------------------------------------------------------------------------------------|------|---------|-------------------------------------|----------|
| 1-(2,2-DIMETHOXYETHYL)-5-METHOXY-6-(METHOXYCARBONYL)-4-OXO-1H-PYRIDINE-3-CARBOXYLIC ACID | 1 kg | 1       | Amino Acetyldehyde Di Methyl Acetal | 0.575 kg |
|                                                                                          |      | 2       | Methyl-4-Methoxy Acetoacetate       | 0.725 kg |
|                                                                                          |      | 3       | Di Methyl Oxalate                   | 1.17 kg  |
|                                                                                          |      | 4       | Lithium Hydroxide                   | 0.300 kg |

RA concerned may take further necessary action as per above decision of NC.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 172 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | VASISTA LIFE SCIENCES PRIVATE LIMITED       |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001902AM23                  |
| RA File Number               | 09AX04000327 AM23                           |
| Licence No and Date          | 0911003295/07/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 173 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SHIVAM ADDITIVES PRIVATE LIMITED            |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001907AM23                  |
| RA File Number               | 05AX04000961 AM23                           |
| Licence No and Date          | 0511013644/07/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 174 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SRF LIMITED                                 |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001911AM23                  |
| RA File Number               | 05AX04001017 AM23                           |
| Licence No and Date          | 0511013648/07/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 175 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | HETERO LABS LIMITED                         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001934AM23                  |

|                                                                                                                                                                                                 |                       |         |                                                                                  |          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------|----------------------------------------------------------------------------------|----------|
| RA File Number                                                                                                                                                                                  | 09AX04000266 AM23     |         |                                                                                  |          |
| Licence No and Date                                                                                                                                                                             | 0911003309/08/07/2022 |         |                                                                                  |          |
| Norms Committee Decision:                                                                                                                                                                       |                       |         |                                                                                  |          |
| The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                       |         |                                                                                  |          |
| Export product                                                                                                                                                                                  | Qty.                  | Sl. No. | Import items                                                                     | Qty.     |
| ATORVASTATIN<br>TRIHYDRATE                                                                                                                                                                      | 1 kg                  | 1       | (4R-CIS)-1,1-DIMETHYL ETHYL-{6-CYANO-METHYL-2,2-DIMETHYL-1,3-DIOXANE}-4- ACETATE | 0.708 kg |
|                                                                                                                                                                                                 |                       | 2       | 4-(4-FLUORO PHENYL)-2-ISOBUTYL-3-PHENYL -4-OXO-PHENYL BUTYRAMIDE                 | 0.994 kg |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                     |                       |         |                                                                                  |          |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 176 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SALVI CHEMICAL INDUSTRIES LIMITED           |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001938AM23                  |
| RA File Number               | 03AX04001943 AM23                           |
| Licence No and Date          | 0311016208/08/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 177 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Deferred                               |
| Party Name              | YASHO INDUSTRIES LIMITED                    |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001947AM23                  |
| RA File Number          | 03AX04002171 AM23                           |
| Licence No and Date     | 0311016221/10/07/2022                       |

Norms Committee Decision:

Deferred for comments of TE.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 178 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | SUN PHARMACEUTICAL INDUSTRIES LIMITED       |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001970AM23                  |
| RA File Number          | 05AX04001047 AM23                           |
| Licence No and Date     | 0511013708/11/07/2022                       |

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jun/202122/2 dated 02/07/2021** against advance authorization No. **0511002328 dated 28/04/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                                                                                                      | Qty.          | Sl. No. | Import items | Qty.      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------|--------------|-----------|
| Nepafenac Ophthalmic Suspension, 0.1% w/v NEPALACT Sterile Eye Drops, 5ml) (PRANAYAM)((Each ml contains Nepafenac 1.0 mg (Equivalent to 300.000 Gram of Bulk Drug)) | 60000 Numbers | 1       | Nepafenac    | 306 grams |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 179 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Deferred                               |
| Party Name              | REYAANSH HEALTHCARE                         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001972AM23                  |
| RA File Number          | 03AX04002163 AM23                           |
| Licence No and Date     | 0311016269/11/07/2022                       |

Norms Committee Decision:

Deferred for comments of TE.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 180 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | AGIO PHARMACEUTICALS LIMITED                |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001974AM23                  |
| RA File Number               | 03AX04001994 AM23                           |
| Licence No and Date          | 0311016274/11/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|                                                                                                                                                                                                                                                                                                                                                                                                             |                                             |                |                           |            |              |      |                                                                                                                                                |                         |   |                           |            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------|---------------------------|------------|--------------|------|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---|---------------------------|------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                    | 181 / NC/3/MEET/Dec/202223/15               |                |                           |            |              |      |                                                                                                                                                |                         |   |                           |            |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                 | Case Approved                               |                |                           |            |              |      |                                                                                                                                                |                         |   |                           |            |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                  | GLENMARK PHARMACEUTICALS LIMITED            |                |                           |            |              |      |                                                                                                                                                |                         |   |                           |            |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                     | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |                           |            |              |      |                                                                                                                                                |                         |   |                           |            |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                              | HQRNORM APPLY 00001953AM23                  |                |                           |            |              |      |                                                                                                                                                |                         |   |                           |            |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                              | 03AX04002116 AM23                           |                |                           |            |              |      |                                                                                                                                                |                         |   |                           |            |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                         | 0311016234/11/07/2022                       |                |                           |            |              |      |                                                                                                                                                |                         |   |                           |            |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                   |                                             |                |                           |            |              |      |                                                                                                                                                |                         |   |                           |            |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Jul/202122/4 dated 15/07/2021</b> against advance authorization No. <b>0311001713 dated 22/02/2021</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |                |                           |            |              |      |                                                                                                                                                |                         |   |                           |            |
| <table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Colesevelam HCL for oral suspension 3.75 GM (Per Pack 30 Pouchs) (Total 3100 Packs)((Net. Content of Colesevelam Hydrochloride is 348.75 kgs))</td><td>3100<br/>Number<br/>Packs</td><td>1</td><td>Colesevelam Hydrochloride</td><td>366.187 kg</td></tr></table>                             |                                             | Export product | Qty.                      | Sl. No.    | Import items | Qty. | Colesevelam HCL for oral suspension 3.75 GM (Per Pack 30 Pouchs) (Total 3100 Packs)((Net. Content of Colesevelam Hydrochloride is 348.75 kgs)) | 3100<br>Number<br>Packs | 1 | Colesevelam Hydrochloride | 366.187 kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                              | Qty.                                        | Sl. No.        | Import items              | Qty.       |              |      |                                                                                                                                                |                         |   |                           |            |
| Colesevelam HCL for oral suspension 3.75 GM (Per Pack 30 Pouchs) (Total 3100 Packs)((Net. Content of Colesevelam Hydrochloride is 348.75 kgs))                                                                                                                                                                                                                                                              | 3100<br>Number<br>Packs                     | 1              | Colesevelam Hydrochloride | 366.187 kg |              |      |                                                                                                                                                |                         |   |                           |            |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                 |                                             |                |                           |            |              |      |                                                                                                                                                |                         |   |                           |            |

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|----------------|---------------------------------------------|
| Case No.       | 182 / NC/3/MEET/Dec/202223/15               |
| Case Status    | Case Approved                               |
| Party Name     | GLOBAL CALCIUM PRIVATE LIMITED              |
| Meeting Number | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |

| and Date                                                                                                                                                                                                                                                                                                                                                                                                          |                            |                |                          |          |              |      |                  |      |   |                       |          |   |                          |          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------|--------------------------|----------|--------------|------|------------------|------|---|-----------------------|----------|---|--------------------------|----------|
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                    | HQRNORM APPLY 00001954AM23 |                |                          |          |              |      |                  |      |   |                       |          |   |                          |          |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                    | 07AX04000520 AM23          |                |                          |          |              |      |                  |      |   |                       |          |   |                          |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                               | 0711004607/11/07/2022      |                |                          |          |              |      |                  |      |   |                       |          |   |                          |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                         |                            |                |                          |          |              |      |                  |      |   |                       |          |   |                          |          |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Jun/202122/2 dated 02/07/2021</b> against advance authorization No. <b>0711000984 dated 27/04/2021</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                            |                |                          |          |              |      |                  |      |   |                       |          |   |                          |          |
| <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">COPPER GLUCONATE</td> <td rowspan="2">1 kg</td> <td>1</td> <td>GLUCONO DELTA LACTONE</td> <td>0.901 kg</td> </tr> <tr> <td>2</td> <td>COPPER OXIDE - ANY GRADE</td> <td>0.225 kg</td> </tr> </tbody> </table>                              |                            | Export product | Qty.                     | Sl. No.  | Import items | Qty. | COPPER GLUCONATE | 1 kg | 1 | GLUCONO DELTA LACTONE | 0.901 kg | 2 | COPPER OXIDE - ANY GRADE | 0.225 kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                    | Qty.                       | Sl. No.        | Import items             | Qty.     |              |      |                  |      |   |                       |          |   |                          |          |
| COPPER GLUCONATE                                                                                                                                                                                                                                                                                                                                                                                                  | 1 kg                       | 1              | GLUCONO DELTA LACTONE    | 0.901 kg |              |      |                  |      |   |                       |          |   |                          |          |
|                                                                                                                                                                                                                                                                                                                                                                                                                   |                            | 2              | COPPER OXIDE - ANY GRADE | 0.225 kg |              |      |                  |      |   |                       |          |   |                          |          |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                       |                            |                |                          |          |              |      |                  |      |   |                       |          |   |                          |          |

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|------------------------------|---------------------------------------------|
| Case No.                     | 183 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | VIPPY INDUSTRIES LIMITED                    |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001956AM23                  |
| RA File Number               | 56AX04000008 AM23                           |
| Licence No and Date          | 5611001042/11/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------|---------------------------------------------|
| Case No.                | 184 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Deferred                               |
| Party Name              | KOPRAN RESEARCH LABORATORIES LIMITED        |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00001959AM23                  |
| RA File Number          | 03AX04002151 AM23                           |
| Licence No and Date     | 0311016241/11/07/2022                       |

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|------------------------------|
| Norms Committee Decision:    |
| Deferred for comments of TE. |

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|------------------------------|---------------------------------------------|
| Case No.                     | 185 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | FRESENIUS KABI ONCOLOGY LIMITED             |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001963AM23                  |
| RA File Number               | 05AX04001045 AM23                           |
| Licence No and Date          | 0511013693/11/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 186 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | BROOKS STERISCIENCE LIMITED                 |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002001AM23                  |
| RA File Number               | 34AX04000225 AM23                           |
| Licence No and Date          | 3411002523/12/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 187 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | KusuMa PharMa                               |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001986AM23                  |
| RA File Number               | 03AX04002093 AM23                           |
| Licence No and Date          | 0311016291/12/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------|---------------------------------|
| Case No.    | 188 / NC/3/MEET/Dec/202223/15   |
| Case Status | Case Deferred                   |
| Party Name  | ALEMBIC PHARMACEUTICALS LIMITED |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00001993AM23                  |
| RA File Number               | 34AX04000353 AM23                           |
| Licence No and Date          | 3411002522/12/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                                                                                                                                                                                                                                                     | 189 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                                                                                  | Case Deferred                               |
| Party Name                                                                                                                                                                                                                                                   | LECILITE INGREDIENTS PRIVATE LIMITED        |
| Meeting Number and Date                                                                                                                                                                                                                                      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                               | HQRNORM APPLY 00001997AM23                  |
| RA File Number                                                                                                                                                                                                                                               | 50AX04000028 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                          | 5011000524/12/07/2022                       |
| Norms Committee Decision:                                                                                                                                                                                                                                    |                                             |
| The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:                                                                                                                              |                                             |
| <p>(i) <b>COA of import item from foreign supplier indicating percentage moisture content.</b></p> <p>(ii) <b>Complete specification of export item.</b></p> <p>(iii) <b>Process of manufacturing indicating wastage at each stage of manufacturing.</b></p> |                                             |

|                                                                                                                                                                       |                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                                                                                                                              | 190 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                           | Case Deferred                               |
| Party Name                                                                                                                                                            | ENCUBE ETHICALS PRIVATE LIMITED             |
| Meeting Number and Date                                                                                                                                               | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                        | HQRNORM APPLY 00001998AM23                  |
| RA File Number                                                                                                                                                        | 03AX04002023 AM23                           |
| Licence No and Date                                                                                                                                                   | 0311016305/12/07/2022                       |
| Norms Committee Decision:                                                                                                                                             |                                             |
| The Committee considered the case as per agenda and it was decided to call the firm for attending <b>Personal Hearing</b> before Norms Committee to explain its case. |                                             |

|             |                               |
|-------------|-------------------------------|
| Case No.    | 191 / NC/3/MEET/Dec/202223/15 |
| Case Status | Case Deferred                 |

|                                                                                                                                                                                                               |                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Party Name                                                                                                                                                                                                    | ENCUBE ETHICALS PRIVATE LIMITED             |
| Meeting Number and Date                                                                                                                                                                                       | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                | HQRNORM APPLY 00001999AM23                  |
| RA File Number                                                                                                                                                                                                | 03AX04002195 AM23                           |
| Licence No and Date                                                                                                                                                                                           | 0311016306/12/07/2022                       |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and it was decided to call the firm for attending <b>Personal Hearing</b> before Norms Committee to explain its case.</p> |                                             |

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| Case No.                                                                                                                                                                                                                                                                                        | 192 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                                                                                                                     | Case Deferred                               |
| Party Name                                                                                                                                                                                                                                                                                      | APEX DRUG HOUSE                             |
| Meeting Number and Date                                                                                                                                                                                                                                                                         | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                  | HQRNORM APPLY 00002007AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                  | 03AX04002053 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                             | 0311016315/13/07/2022                       |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:</p> <p style="text-align: center;">(i) <b>DML.</b></p> <p style="text-align: center;">(ii) <b>Master Batch Formula.</b></p> |                                             |

|                                                                      |                                             |
|----------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                             | 193 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                          | Case Deferred                               |
| Party Name                                                           | AMI ORGANICS LIMITED                        |
| Meeting Number and Date                                              | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                       | HQRNORM APPLY 00002011AM23                  |
| RA File Number                                                       | 52AX04001578 AM23                           |
| Licence No and Date                                                  | 5211002817/13/07/2022                       |
| <p>Norms Committee Decision:</p> <p>Deferred for comments of TE.</p> |                                             |

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| Case No.    | 194 / NC/3/MEET/Dec/202223/15 |
| Case Status | Case Deferred                 |

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|------------------------------|---------------------------------------------|
| Party Name                   | AUORE LIFE SCIENCES PRIVATE LIMITED         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002017AM23                  |
| RA File Number               | 09AX04000301 AM23                           |
| Licence No and Date          | 0911003338/13/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 195 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | AUORE LIFE SCIENCES PRIVATE LIMITED         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002018AM23                  |
| RA File Number               | 09AX04000333 AM23                           |
| Licence No and Date          | 0911003339/13/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 196 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | AUORE LIFE SCIENCES PRIVATE LIMITED         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002019AM23                  |
| RA File Number               | 09AX04000338 AM23                           |
| Licence No and Date          | 0911003340/13/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------|---------------------------------------------|
| Case No.                | 197 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Deferred                               |
| Party Name              | SRF LIMITED                                 |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002026AM23                  |
| RA File Number          | 05AX04001011 AM23                           |
| Licence No and Date     | 0511013749/13/07/2022                       |

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| Norms Committee Decision:    |
| Deferred for comments of TE. |

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|------------------------------|---------------------------------------------|
| Case No.                     | 198 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | DEEPAK NITRITE LIMITED                      |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002027AM23                  |
| RA File Number               | 34AX04000357 AM23                           |
| Licence No and Date          | 3411002528/13/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 199 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | FREESIA CHEMICALS                           |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002037AM23                  |
| RA File Number               | 03AX04002018 AM23                           |
| Licence No and Date          | 0311016342/14/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 200 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | FRESENIUS KABI ONCOLOGY LIMITED             |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002039AM23                  |
| RA File Number               | 05AX04001046 AM23                           |
| Licence No and Date          | 0511013764/14/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------|-------------------------------|
| Case No.    | 201 / NC/3/MEET/Dec/202223/15 |
| Case Status | Case Approved                 |
| Party Name  | ALTA LABORATORIES LIMITED     |

| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                   | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |         |                           |         |                |      |         |              |      |                |      |   |                           |         |   |          |         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------|---------------------------|---------|----------------|------|---------|--------------|------|----------------|------|---|---------------------------|---------|---|----------|---------|
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                            | HQRNORM APPLY 00002041AM23                  |         |                           |         |                |      |         |              |      |                |      |   |                           |         |   |          |         |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                            | 03AX04002260 AM23                           |         |                           |         |                |      |         |              |      |                |      |   |                           |         |   |          |         |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                       | 0311016346/14/07/2022                       |         |                           |         |                |      |         |              |      |                |      |   |                           |         |   |          |         |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                 |                                             |         |                           |         |                |      |         |              |      |                |      |   |                           |         |   |          |         |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>3/82-ALC4/2018 dated 05.06.2018</b> against advance authorization No. <b>0310803707 dated 01/04/2016</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                                             |         |                           |         |                |      |         |              |      |                |      |   |                           |         |   |          |         |
| <table border="1"> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> <tr> <td rowspan="2">METHYL PARABEN</td> <td rowspan="2">1 kg</td> <td>1</td> <td>PARA HYDROXY BENZOIC ACID</td> <td>0.97 kg</td> </tr> <tr> <td>2</td> <td>METHANOL</td> <td>0.50 kg</td> </tr> </table>                                                                        |                                             |         |                           |         | Export product | Qty. | Sl. No. | Import items | Qty. | METHYL PARABEN | 1 kg | 1 | PARA HYDROXY BENZOIC ACID | 0.97 kg | 2 | METHANOL | 0.50 kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                            | Qty.                                        | Sl. No. | Import items              | Qty.    |                |      |         |              |      |                |      |   |                           |         |   |          |         |
| METHYL PARABEN                                                                                                                                                                                                                                                                                                                                                                                            | 1 kg                                        | 1       | PARA HYDROXY BENZOIC ACID | 0.97 kg |                |      |         |              |      |                |      |   |                           |         |   |          |         |
|                                                                                                                                                                                                                                                                                                                                                                                                           |                                             | 2       | METHANOL                  | 0.50 kg |                |      |         |              |      |                |      |   |                           |         |   |          |         |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                               |                                             |         |                           |         |                |      |         |              |      |                |      |   |                           |         |   |          |         |

|                              |                                             |  |  |  |
|------------------------------|---------------------------------------------|--|--|--|
| Case No.                     | 202 / NC/3/MEET/Dec/202223/15               |  |  |  |
| Case Status                  | Case Deferred                               |  |  |  |
| Party Name                   | CLEAN SCIENCE AND TECHNOLOGY LIMITED        |  |  |  |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |  |  |  |
| HQ File Number               | HQRNORM APPLY 00002045AM23                  |  |  |  |
| RA File Number               | 31AX04000111 AM23                           |  |  |  |
| Licence No and Date          | 3111001563/14/07/2022                       |  |  |  |
| Norms Committee Decision:    |                                             |  |  |  |
| Deferred for comments of TE. |                                             |  |  |  |

|                         |                                             |  |  |  |
|-------------------------|---------------------------------------------|--|--|--|
| Case No.                | 203 / NC/3/MEET/Dec/202223/15               |  |  |  |
| Case Status             | Case Approved                               |  |  |  |
| Party Name              | AUROBINDO PHARMA LTD                        |  |  |  |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |  |  |  |
| HQ File Number          | HQRNORM APPLY 00002090AM23                  |  |  |  |
| RA File Number          | 09AX04000340 AM23                           |  |  |  |
| Licence No and          | 0911003357/15/07/2022                       |  |  |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                           |          |         |                                       |                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|---------------------------------------|--------------------------|
| Date                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                           |          |         |                                       |                          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                           |          |         |                                       |                          |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Nov/202223/12 dated 18/11/2022</b> against advance authorization No. <b>0911002654 dated 11/03/2022</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                                                                                                                                                           |          |         |                                       |                          |
| Sl. No.                                                                                                                                                                                                                                                                                                                                                                                                            | Export product                                                                                                                                            | Qty.     | Sl. No. | Import items                          | Qty.                     |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                  | Cefalexin Tablets 250mg(Cephalexin Tablets 250mg (Each film coated tablet contains Cefalexin Monohydrate Ph.Eur equivalent to anhydrous Cefalexin 250mg)) | 1 Number | 1       | Cefalexin Monohydrate Ph Eur (Powder) | 268.2 mg / 250 mg Tablet |
| 2                                                                                                                                                                                                                                                                                                                                                                                                                  | Cefalexin Tablets 500mg(Cephalexin Tablets 500mg (Each film coated tablet contains Cefalexin Monohydrate Ph.Eur equivalent to anhydrous Cefalexin 500mg)) | 1 Number | 2       | Cefalexin Monohydrate Ph Eur (Powder) | 536.4 mg / 500 mg Tablet |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                           |          |         |                                       |                          |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 204 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | ALTA LABORATORIES LIMITED                   |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002061AM23                  |
| RA File Number               | 03AX04002261 AM23                           |
| Licence No and Date          | 0311016368/15/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------|---------------------------------------------|
| Case No.                | 205 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Deferred                               |
| Party Name              | BHARAT PARENTERALS LIMITED                  |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002066AM23                  |

|                              |                       |
|------------------------------|-----------------------|
| RA File Number               | 34AX04000345 AM23     |
| Licence No and Date          | 3411002534/15/07/2022 |
| Norms Committee Decision:    |                       |
| Deferred for comments of TE. |                       |

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|------------------------------|---------------------------------------------|
| Case No.                     | 206 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | ALEOR DERMACEUTICALS LIMITED                |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002067AM23                  |
| RA File Number               | 34AX04000361 AM23                           |
| Licence No and Date          | 3411002535/15/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 207 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | AUROBINDO PHARMA LTD                        |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002087AM23                  |
| RA File Number               | 09AX04000341 AM23                           |
| Licence No and Date          | 0911003356/15/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                                                                                                                                                                                                   | 208 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                                                                | Case Approved                               |
| Party Name                                                                                                                                                                                                                                 | GLENMARK LIFE SCIENCES LIMITED              |
| Meeting Number and Date                                                                                                                                                                                                                    | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                             | HQRNORM APPLY 00002110AM23                  |
| RA File Number                                                                                                                                                                                                                             | 03AX04002251 AM23                           |
| Licence No and Date                                                                                                                                                                                                                        | 0311016413/18/07/2022                       |
| Norms Committee Decision:                                                                                                                                                                                                                  |                                             |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>2/82-ALC4/2020 dated 10.07.2020</b> against advance authorization No. <b>0310834853 dated</b> |                                             |

**13.02.2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export Product       | Qty. | Sl. No. | Import items                     | Qty.     |
|----------------------|------|---------|----------------------------------|----------|
| PERINDOPRIL ERBUMINE | 1 kg | 1       | S-(-)-INDOLINE-2-CARBOXYLIC ACID | 0.947 kg |
|                      |      | 2       | L-NORVALINE                      | 1.423 kg |
|                      |      | 3       | ACETONITRILE                     | 6.345 kg |
|                      |      | 4       | N,N-CARBONYLDIIMIDAZOLE          | 0.700 kg |
|                      |      | 5       | METHYLENE CHLORIDE (MDC)         | 6.260 kg |
|                      |      | 6       | SODIUM PYRUVATE                  | 1.42 kg  |
|                      |      | 7       | METHANOL                         | 10.80 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 209 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | PI INDUSTRIES LIMITED                       |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002152AM23                  |
| RA File Number          | 13AX04000110 AM23                           |
| Licence No and Date     | 1311001336/19/07/2022                       |

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export Product | Qty. | Sl. No. | Import items | Qty. |
|----------------|------|---------|--------------|------|
|----------------|------|---------|--------------|------|

|                                                                                                                              |      |   |                                        |          |
|------------------------------------------------------------------------------------------------------------------------------|------|---|----------------------------------------|----------|
| 1-(3-Chloro-4,5,6,7-tetrahydropyrazolo[1,5-a]pyridin-2-yl)-5-[methyl(prop-2-ynyl)amino]pyrazole-4-carbonitrile((PYRACLONIL)) | 1 kg | 1 | Malononitrile                          | 0.555 kg |
|                                                                                                                              |      | 2 | Trimethylorthoformate                  | 1.972 kg |
|                                                                                                                              |      | 3 | 1, 1, 7-trichloro-1-hepten-3-one       | 1.263 kg |
|                                                                                                                              |      | 4 | Hydrazine Hydrate                      | 1.998 kg |
|                                                                                                                              |      | 5 | Propargyl chloride 65% Xylene Solution | 0.668 kg |

RA concerned may take further necessary action as per above decision of NC.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 210 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SOLARA ACTIVE PHARMA SCIENCES LIMITED       |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002153AM23                  |
| RA File Number               | 04AX04000366 AM23                           |
| Licence No and Date          | 0411003672/19/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                                                                                                                                                        | 211 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                     | Case Approved                               |
| Party Name                                                                                                                                                                                      | MAIVA PHARMA PRIVATE LIMITED                |
| Meeting Number and Date                                                                                                                                                                         | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                  | HQRNORM APPLY 00002127AM23                  |
| RA File Number                                                                                                                                                                                  | 07AX04000549 AM23                           |
| Licence No and Date                                                                                                                                                                             | 0711004623/19/07/2022                       |
| Norms Committee Decision:                                                                                                                                                                       |                                             |
| The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |

| Export Product                                | Qty.     | Sl. No. | Import items                                                                                | Qty.                              |
|-----------------------------------------------|----------|---------|---------------------------------------------------------------------------------------------|-----------------------------------|
| Metochlopramide Injection<br>5mg/mL, 2mL vial | 1 Number | 1       | V-35 4031/45G DC SIL WesterSELECT RS<br>P02(13mm Serum Non laminated Bromobutyl<br>R/S RFS) | Relevant as per<br>packing policy |

RA concerned may take further necessary action as per above decision of NC.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 212 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | YASHO INDUSTRIES LIMITED                    |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002130AM23                  |
| RA File Number               | 03AX04002326 AM23                           |
| Licence No and Date          | 0311016439/19/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 213 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SYMBIOTEC PHARMALAB PRIVATE LIMITED         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002133AM23                  |
| RA File Number               | 56AX04000094 AM23                           |
| Licence No and Date          | 5611001068/19/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------|---------------------------------------------|
| Case No.                | 214 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | BALAJI SPECIALITY CHEMICALS LIMITED         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002137AM23                  |
| RA File Number          | 31AX04000114 AM23                           |
| Licence No and Date     | 3111001569/19/07/2022                       |

## Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Mar/202122/15 dated 10.07.2020** against advance authorization No. **3111000148 dated 09-02-2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                          | Qty. | Sl. No. | Import items       | Qty.                                   |
|-----------------------------------------|------|---------|--------------------|----------------------------------------|
| ETHYLENE DI AMINE<br>(ORGANIC CHEMICAL) | 1 kg | 1       | MONO ETHANOL AMINE | 1.0374 kg                              |
|                                         |      | 2       | AMMONIA ANHYDROUS  | Not allowed, as it is shown indigenous |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 215 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | DEEPAK PHENOLICS LIMITED                    |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002141AM23                  |
| RA File Number          | 34AX04000380 AM23                           |
| Licence No and Date     | 3411002553/19/07/2022                       |

## Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **3411002081 dated 31/03/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product | Qty. | Sl. No. | Import items | Qty.       |
|----------------|------|---------|--------------|------------|
| Phenol         | 1 MT | 1       | Cumene       | 0.84466 MT |

RA concerned may take further necessary action as per above decision of NC.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 216 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | ADCOCK INGRAM LIMITED                       |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002158AM23                  |
| RA File Number               | 07AX04000582 AM23                           |
| Licence No and Date          | 0711004714/20/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 217 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | GLENMARK LIFE SCIENCES LIMITED              |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002159AM23                  |
| RA File Number               | 03AX04002253 AM23                           |
| Licence No and Date          | 0311016458/20/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 218 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | HETERO LABS LIMITED                         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002166AM23                  |
| RA File Number               | 09AX04000298 AM23                           |
| Licence No and Date          | 0911003371/20/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------|---------------------------------------------|
| Case No.                | 219 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | GLOBAL CALCIUM PRIVATE LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002173AM23                  |

|                                                                                                                                                                                                                                                                                                                                                                                                           |                              |      |         |                           |          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|------|---------|---------------------------|----------|
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                            | 07AX04000562 AM23            |      |         |                           |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                       | 0711004736/21/07/2022        |      |         |                           |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                 |                              |      |         |                           |          |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>3/82-ALC4/2019 dated 05.07.2019</b> against advance authorization No. <b>0710113808 dated 03.09.2018</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                              |      |         |                           |          |
| Sl. No.                                                                                                                                                                                                                                                                                                                                                                                                   | Export product               | Qty. | Sl. No. | Import items              | Qty.     |
| 1                                                                                                                                                                                                                                                                                                                                                                                                         | MAGNESIUM ASCORBATE          | 1 kg | 1       | ASCORBIC ACID - ANY GRADE | 1.1 kg   |
| 2                                                                                                                                                                                                                                                                                                                                                                                                         | CALCIUM ASCORBATE (BP/USP)   | 1 kg | 1       | ASCORBIC ACID - ANY GRADE | 0.964 kg |
| 3                                                                                                                                                                                                                                                                                                                                                                                                         | ZINC ASCORBATE               | 1 kg | 1       | ASCORBIC ACID - ANY GRADE | 0.989 kg |
| 4                                                                                                                                                                                                                                                                                                                                                                                                         | SODIUM ASCORBATE (BP/EP/USP) | 1 kg | 1       | ASCORBIC ACID - ANY GRADE | 1.03 kg  |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                               |                              |      |         |                           |          |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 220 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | ASTEC LIFESCIENCES LIMITED                  |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002174AM23                  |
| RA File Number               | 03AX04002330 AM23                           |
| Licence No and Date          | 0311016485/21/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------|-------------------------------|
| Case No.    | 221 / NC/3/MEET/Dec/202223/15 |
| Case Status | Case Deferred                 |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Party Name                   | JUBILANT INGREVIA LIMITED                   |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002179AM23                  |
| RA File Number               | 05AX04001164 AM23                           |
| Licence No and Date          | 0511013888/21/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------|------------------|----------|----------------|------|---------|--------------|------|---------------------|------|---|------------------|----------|
| Case No.                                                                                                                                                                                                             | 222 / NC/3/MEET/Dec/202223/15               |         |                  |          |                |      |         |              |      |                     |      |   |                  |          |
| Case Status                                                                                                                                                                                                          | Case Approved                               |         |                  |          |                |      |         |              |      |                     |      |   |                  |          |
| Party Name                                                                                                                                                                                                           | SHIVA PHARMACHEM LIMITED                    |         |                  |          |                |      |         |              |      |                     |      |   |                  |          |
| Meeting Number and Date                                                                                                                                                                                              | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |         |                  |          |                |      |         |              |      |                     |      |   |                  |          |
| HQ File Number                                                                                                                                                                                                       | HQRNORM APPLY 00002182AM23                  |         |                  |          |                |      |         |              |      |                     |      |   |                  |          |
| RA File Number                                                                                                                                                                                                       | 34AX04000379 AM23                           |         |                  |          |                |      |         |              |      |                     |      |   |                  |          |
| Licence No and Date                                                                                                                                                                                                  | 3411002560/21/07/2022                       |         |                  |          |                |      |         |              |      |                     |      |   |                  |          |
| Norms Committee Decision:                                                                                                                                                                                            |                                             |         |                  |          |                |      |         |              |      |                     |      |   |                  |          |
| The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:                      |                                             |         |                  |          |                |      |         |              |      |                     |      |   |                  |          |
| <table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>1,6 DICHLORO HEXANE</td><td>1 kg</td><td>1</td><td>1, 6 HEXANE DIOL</td><td>0.846 kg</td></tr></table> |                                             |         |                  |          | Export product | Qty. | Sl. No. | Import items | Qty. | 1,6 DICHLORO HEXANE | 1 kg | 1 | 1, 6 HEXANE DIOL | 0.846 kg |
| Export product                                                                                                                                                                                                       | Qty.                                        | Sl. No. | Import items     | Qty.     |                |      |         |              |      |                     |      |   |                  |          |
| 1,6 DICHLORO HEXANE                                                                                                                                                                                                  | 1 kg                                        | 1       | 1, 6 HEXANE DIOL | 0.846 kg |                |      |         |              |      |                     |      |   |                  |          |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                          |                                             |         |                  |          |                |      |         |              |      |                     |      |   |                  |          |

|                           |                                             |
|---------------------------|---------------------------------------------|
| Case No.                  | 223 / NC/3/MEET/Dec/202223/15               |
| Case Status               | Case Approved                               |
| Party Name                | DEEPAK PHENOLICS LIMITED                    |
| Meeting Number and Date   | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number            | HQRNORM APPLY 00002184AM23                  |
| RA File Number            | 34AX04000393 AM23                           |
| Licence No and Date       | 3411002562/21/07/2022                       |
| Norms Committee Decision: |                                             |

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **3411002081 dated 31/03/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product | Qty. | Sl. No. | Import items | Qty.       |
|----------------|------|---------|--------------|------------|
| Phenol         | 1 MT | 1       | Cumene       | 0.84466 MT |

RA concerned may take further necessary action as per above decision of NC.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 224 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | HETERO LABS LIMITED                         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002168AM23                  |
| RA File Number               | 09AX04000297 AM23                           |
| Licence No and Date          | 0911003374/21/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                    | 225 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                 | Case Approved                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                  | DIAMINES AND CHEMICALS LIMITED              |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                     | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                              | HQRNORM APPLY 00002185AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                              | 34AX04000385 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                         | 3411002568/21/07/2022                       |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                   |                                             |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Sep/202223/9 dated 07/10/2022</b> against advance authorization No. <b>3411000643 dated 27/05/2021</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |

| Export Product       | Qty  | Sl. No. | Import Item Name.                                                       | Qty.     |
|----------------------|------|---------|-------------------------------------------------------------------------|----------|
| PIPERAZINE ANHYDROUS | 1 kg | 1       | PIPERAZINE CRUDE OR PIPERAZINE MIXTURE<br>(Percentage purity NMT 48.1%) | 2.047 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 226 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | GLOBAL CALCIUM PRIVATE LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002171AM23                  |
| RA File Number          | 07AX04000558 AM23                           |
| Licence No and Date     | 0711004734/21/07/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product            | Qty. | Sl. No. | Import items                   | Qty.     |
|---------------------------|------|---------|--------------------------------|----------|
| CALCIUM LACTATE GLUCONATE | 1 kg | 1       | CALCIUM LACTATE - PENTAHYDRATE | 0.47 kg  |
|                           |      | 2       | CALCIUM GLUCONATE              | 0.642 kg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 227 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | HONOUR LAB LIMITED                          |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002186AM23                  |

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| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                     | 09AX04000263 AM23     |         |                                     |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                | 0911003377/21/07/2022 |         |                                     |          |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                          |                       |         |                                     |          |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Nov/202223/12 dated 18/11/2022</b> against advance authorization No. <b>0911002884 dated 21/04/2022</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                       |         |                                     |          |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                     | Qty.                  | Sl. No. | Import items                        | Qty.     |
| 1-(2,2-DIMETHOXYETHYL)-5-METHOXY-6-(METHOXYCARBONYL)-4-OXO-1H-PYRIDINE-3-CARBOXYLIC ACID                                                                                                                                                                                                                                                                                                                           | 1 kg                  | 1       | Amino Acetyldehyde Di Methyl Acetal | 0.575 kg |
|                                                                                                                                                                                                                                                                                                                                                                                                                    |                       | 2       | Methyl-4-Methoxy Acetoacetate       | 0.725 kg |
|                                                                                                                                                                                                                                                                                                                                                                                                                    |                       | 3       | Di Methyl Oxalate                   | 1.17 kg  |
|                                                                                                                                                                                                                                                                                                                                                                                                                    |                       | 4       | Lithium Hydroxide                   | 0.300 kg |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                        |                       |         |                                     |          |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                   | 228 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                | Case Approved                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                 | GLOBAL CALCIUM PRIVATE LIMITED              |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                    | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                             | HQRNORM APPLY 00002172AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                             | 07AX04000561 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                        | 0711004735/21/07/2022                       |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                  |                                             |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>13/82-ALC4/2019 dated 31/01/2020</b> against advance authorization No. <b>0710114346 dated 31.12.2018</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                                             |

| Export product                                                                                       | Qty. | Sl. No. | Import items   | Qty.    |
|------------------------------------------------------------------------------------------------------|------|---------|----------------|---------|
| CALCIUM LEVULINATE / CALCIUM LEVULINATE DIHYDRATE BP/ CALCIUM LEVULINATE EP / CALCIUM LEVULINATE USP | 1 kg | 1       | LEVULINIC ACID | 1.02 kg |

RA concerned may take further necessary action as per above decision of NC.

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|------------------------------|---------------------------------------------|
| Case No.                     | 229 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | STYRAX LIFE SCIENCES PRIVATE LIMITED        |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002187AM23                  |
| RA File Number               | 09AX04000313 AM23                           |
| Licence No and Date          | 0911003379/21/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 230 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | BELCHEM INDUSTRIES (INDIA) PVT LTD          |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002202AM23                  |
| RA File Number               | 03AX04002190 AM23                           |
| Licence No and Date          | 0311016511/22/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------|---------------------------------------------|
| Case No.                | 231 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | TRANSPEK INDUSTRY LIMITED                   |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002206AM23                  |
| RA File Number          | 34AX04000364 AM23                           |
| Licence No and          | 3411002574/22/07/2022                       |

|                                                                                                                                                                                                 |      |         |                     |         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|---------|---------------------|---------|
| Date                                                                                                                                                                                            |      |         |                     |         |
| Norms Committee Decision:                                                                                                                                                                       |      |         |                     |         |
| The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |      |         |                     |         |
| Export product                                                                                                                                                                                  | Qty. | Sl. No. | Import items        | Qty.    |
| 4-CHLOROBUTYRYL CHLORIDE                                                                                                                                                                        | 1 kg | 1       | GAMMA BUTYROLACTONE | 0.73 kg |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                     |      |         |                     |         |

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|------------------------------|---------------------------------------------|
| Case No.                     | 232 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SRF LIMITED                                 |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002213AM23                  |
| RA File Number               | 05AX04001131 AM23                           |
| Licence No and Date          | 0511013929/22/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 233 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | CANPEX CHEMICALS PRIVATE LIMITED            |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002216AM23                  |
| RA File Number               | 31AX04000115 AM23                           |
| Licence No and Date          | 3111001583/22/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.    | 234 / NC/3/MEET/Dec/202223/15 |
| Case Status | Case Deferred                 |
| Party Name  | AUROBINDO PHARMA LTD          |

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|------------------------------|---------------------------------------------|
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002217AM23                  |
| RA File Number               | 09AX04000373 AM23                           |
| Licence No and Date          | 0911003393/22/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 235 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | GLOBAL CALCIUM PRIVATE LIMITED              |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002221AM23                  |
| RA File Number               | 07AX04000559 AM23                           |
| Licence No and Date          | 0711004755/23/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                    | 236 / NC/3/MEET/Dec/202223/15               |                |                       |         |              |      |                                    |      |   |                       |         |  |  |  |  |  |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                 | Case Approved                               |                |                       |         |              |      |                                    |      |   |                       |         |  |  |  |  |  |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                  | GLOBAL CALCIUM PRIVATE LIMITED              |                |                       |         |              |      |                                    |      |   |                       |         |  |  |  |  |  |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                     | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |                       |         |              |      |                                    |      |   |                       |         |  |  |  |  |  |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                              | HQRNORM APPLY 00002222AM23                  |                |                       |         |              |      |                                    |      |   |                       |         |  |  |  |  |  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                              | 07AX04000560 AM23                           |                |                       |         |              |      |                                    |      |   |                       |         |  |  |  |  |  |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                         | 0711004756/23/07/2022                       |                |                       |         |              |      |                                    |      |   |                       |         |  |  |  |  |  |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                   |                                             |                |                       |         |              |      |                                    |      |   |                       |         |  |  |  |  |  |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>8/82-ALC4/2018 dated 31/08/2018</b> against advance authorization No. <b>0710112478 d</b> <b>ated 30.11.2017</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |                |                       |         |              |      |                                    |      |   |                       |         |  |  |  |  |  |
| <table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>CALCIUM GLUCOHEPTONATE (BP/Eur.Ph)</td><td>1 kg</td><td>1</td><td>SODIUM GLUCOHEPTONATE</td><td>1.49 kg</td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table>                                                                                                               |                                             | Export product | Qty.                  | Sl. No. | Import items | Qty. | CALCIUM GLUCOHEPTONATE (BP/Eur.Ph) | 1 kg | 1 | SODIUM GLUCOHEPTONATE | 1.49 kg |  |  |  |  |  |
| Export product                                                                                                                                                                                                                                                                                                                                                                                              | Qty.                                        | Sl. No.        | Import items          | Qty.    |              |      |                                    |      |   |                       |         |  |  |  |  |  |
| CALCIUM GLUCOHEPTONATE (BP/Eur.Ph)                                                                                                                                                                                                                                                                                                                                                                          | 1 kg                                        | 1              | SODIUM GLUCOHEPTONATE | 1.49 kg |              |      |                                    |      |   |                       |         |  |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                             |                                             |                |                       |         |              |      |                                    |      |   |                       |         |  |  |  |  |  |

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|--|--|---|-------------------|----------|
|  |  | 2 | CALCIUM CARBONATE | 0.203 kg |
|--|--|---|-------------------|----------|

RA concerned may take further necessary action as per above decision of NC.

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|------------------------------|---------------------------------------------|
| Case No.                     | 237 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | KOPRAN RESEARCH LABORATORIES LIMITED        |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002228AM23                  |
| RA File Number               | 03AX04002208 AM23                           |
| Licence No and Date          | 0311016558/25/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                    | 238 / NC/3/MEET/Dec/202223/15               |                |              |         |              |      |                         |      |   |             |         |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                 | Case Approved                               |                |              |         |              |      |                         |      |   |             |         |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                  | INDO AMINES LIMITED                         |                |              |         |              |      |                         |      |   |             |         |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                     | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |              |         |              |      |                         |      |   |             |         |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                              | HQRNORM APPLY 00002230AM23                  |                |              |         |              |      |                         |      |   |             |         |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                              | 03AX04002387 AM23                           |                |              |         |              |      |                         |      |   |             |         |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                         | 0311016562/25/07/2022                       |                |              |         |              |      |                         |      |   |             |         |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                   |                                             |                |              |         |              |      |                         |      |   |             |         |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Sep/202223/9 dated 07/10/2022</b> against advance authorization No. <b>0311011782 dated 25/02/2022</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |                |              |         |              |      |                         |      |   |             |         |
| <table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>IAL LAD OR LAURYL AMINE</td><td>1 kg</td><td>1</td><td>LAURIC ACID</td><td>1.48 kg</td></tr></table>                                                                                                                                                                                          |                                             | Export product | Qty.         | Sl. No. | Import items | Qty. | IAL LAD OR LAURYL AMINE | 1 kg | 1 | LAURIC ACID | 1.48 kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                              | Qty.                                        | Sl. No.        | Import items | Qty.    |              |      |                         |      |   |             |         |
| IAL LAD OR LAURYL AMINE                                                                                                                                                                                                                                                                                                                                                                                     | 1 kg                                        | 1              | LAURIC ACID  | 1.48 kg |              |      |                         |      |   |             |         |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                 |                                             |                |              |         |              |      |                         |      |   |             |         |

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|-------------------------|---------------------------------------------|
| Case No.                | 239 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | ANUH PHARMA LIMITED                         |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002231AM23                  |
| RA File Number          | 03AX04002324 AM23                           |
| Licence No and Date     | 0311016564/25/07/2022                       |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **13/82-ALC4/2018 dated 14/01/2019** against advance authorization No. **0510407414 dated 02/08/2018**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                              | Qty. | Sl. No. | Import items                                    | Qty.    |
|---------------------------------------------|------|---------|-------------------------------------------------|---------|
| Dexamethasone Sodium Phosphate BP/USP/IP/EP | 1 kg | 1       | Dexamethasone (Dexamethasone Base) BP/USP/IP/EP | 0.78 kg |

RA concerned may take further necessary action as per above decision of NC.

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|-------------------------|---------------------------------------------|
| Case No.                | 240 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Deferred                               |
| Party Name              | VASUDHA PHARMA CHEM LIMITED                 |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002239AM23                  |
| RA File Number          | 26AX04000026 AM23                           |
| Licence No and Date     | 2611000646/25/07/2022                       |

**Norms Committee Decision:**

Deferred for comments of TE.

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|-------------------------|---------------------------------------------|
| Case No.                | 241 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Deferred                               |
| Party Name              | VASUDHA PHARMA CHEM LIMITED                 |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002240AM23                  |

|                              |                       |
|------------------------------|-----------------------|
| RA File Number               | 26AX04000027 AM23     |
| Licence No and Date          | 2611000647/25/07/2022 |
| Norms Committee Decision:    |                       |
| Deferred for comments of TE. |                       |

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|------------------------------|---------------------------------------------|
| Case No.                     | 242 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | HETERO LABS LIMITED                         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002246AM23                  |
| RA File Number               | 09AX04000299 AM23                           |
| Licence No and Date          | 0911003396/25/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                     | 243 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                  | Case Approved                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                   | AARTI DRUGS LIMITED                         |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                               | HQRNORM APPLY 00002227AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                               | 03AX04002310 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                          | 0311016557/25/07/2022                       |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                    |                                             |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Nov/202223/12 dated 18/11/2022</b> against advance authorization No. <b>0311013055 dated 17/03/2022</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |
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RA concerned may take further necessary action as per above decision of NC.

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| Case No.                     | 244 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | KAIRAV CHEMOFARBE INDUSTRIES LIMITED        |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002265AM23                  |
| RA File Number               | 03AX04002336 AM23                           |
| Licence No and Date          | 0311016601/26/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                     | 245 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | FDC LIMITED                                 |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002269AM23                  |
| RA File Number               | 03AX04002211 AM23                           |
| Licence No and Date          | 0311016614/26/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                     | 246 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SOHAN HEALTHCARE PRIVATE LIMITED            |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002279AM23                  |
| RA File Number               | 31AX04000122 AM23                           |
| Licence No and Date          | 3111001586/26/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.    | 247 / NC/3/MEET/Dec/202223/15 |
| Case Status | Case Deferred                 |

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| Party Name                                                                                                                                                                                                    | ENCUBE ETHICALS PRIVATE LIMITED             |
| Meeting Number and Date                                                                                                                                                                                       | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                | HQRNORM APPLY 00002280AM23                  |
| RA File Number                                                                                                                                                                                                | 03AX04002424 AM23                           |
| Licence No and Date                                                                                                                                                                                           | 0311016629/26/07/2022                       |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and it was decided to call the firm for attending <b>Personal Hearing</b> before Norms Committee to explain its case.</p> |                                             |

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| Case No.                                                             | 248 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                          | Case Deferred                               |
| Party Name                                                           | SOHAN HEALTHCARE PRIVATE LIMITED            |
| Meeting Number and Date                                              | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                       | HQRNORM APPLY 00002282AM23                  |
| RA File Number                                                       | 31AX04000121 AM23                           |
| Licence No and Date                                                  | 3111001587/26/07/2022                       |
| <p>Norms Committee Decision:</p> <p>Deferred for comments of TE.</p> |                                             |

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| Case No.                                                             | 249 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                          | Case Deferred                               |
| Party Name                                                           | AUROBINDO PHARMA LTD                        |
| Meeting Number and Date                                              | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                       | HQRNORM APPLY 00002284AM23                  |
| RA File Number                                                       | 09AX04000361 AM23                           |
| Licence No and Date                                                  | 0911003407/26/07/2022                       |
| <p>Norms Committee Decision:</p> <p>Deferred for comments of TE.</p> |                                             |

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| Case No.                | 250 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Deferred                               |
| Party Name              | ASMEE CHEMICALS PRIVATE LIMITED             |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002262AM23                  |
| RA File Number          | 03AX04002314 AM23                           |
| Licence No and          | 0311016599/26/07/2022                       |

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| Date                         |  |
| Norms Committee Decision:    |  |
| Deferred for comments of TE. |  |

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| Case No.                     | 251 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | ASCENT FINECHEM PRIVATE LIMITED             |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002286AM23                  |
| RA File Number               | 08AX04000679 AM23                           |
| Licence No and Date          | 0811005628/26/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                     | 252 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                  | Case Approved                               |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                   | CIPLA LIMITED                               |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                               | HQRNORM APPLY 00002264AM23                  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                               | 03AX04002105 AM23                           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                          | 0311016600/26/07/2022                       |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                    |                                             |
| The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>10/AM20 dated 29.11.2019</b> against advance authorization No. <b>0310822432 dated 19.07.2018</b> , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: |                                             |
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|   |                                                                                                                                                                                                                                                  |                  | 4 | 115CC HDPE BOTTLES 75 ML (250/62.5)                | Relevant as per packing policy |
|   |                                                                                                                                                                                                                                                  |                  | 5 | 28-400 WHITE CLIC LOC CAP WITH PRINTED FSM-1       |                                |
|   |                                                                                                                                                                                                                                                  |                  | 6 | Cap 28/400 WHT CRC W/FS M-I WITH INDUCTION SEALING |                                |
| 2 | Amoxicillin and Clavulanate Potassium for Oral Suspension USP 250mg / 62.5mg (Pack Size 100ml) (Each 5ml contains: Amoxycillin Trihydrate USP equivalent to Amoxicillin 250mg, Clavulanate Potassium USP equivalent to Clavulanic Acid 62.50mg ) | 1000 Number Pack | 1 | Amoxycillin Trihydrate                             | 5.649 kg                       |
|   |                                                                                                                                                                                                                                                  |                  | 2 | CLAVULANATE POTASSIUM WITH SILICON DIOXIDE 1:1     | 3.126 kg                       |
|   |                                                                                                                                                                                                                                                  |                  | 3 | SILICONE DIOXIDE(SYLOID 244FP)                     | 2.00 kg                        |
|   |                                                                                                                                                                                                                                                  |                  | 4 | 115CC HDPE BOTTLES 75 ML (250/62.5)                | Relevant as per packing policy |
|   |                                                                                                                                                                                                                                                  |                  | 5 | 28-400 WHITE CLIC LOC CAP WITH PRINTED FSM-1       |                                |
|   |                                                                                                                                                                                                                                                  |                  | 6 | Cap 28/400 WHT CRC W/FS M-I WITH INDUCTION SEALING |                                |
| 3 | Amoxicillin and Clavulanate Potassium for Oral Suspension USP 250mg / 62.5mg (Pack Size 150ml) (Each 5ml contains: Amoxycillin Trihydrate USP equivalent to Amoxicillin 250mg, Clavulanate Potassium USP equivalent to Clavulanic Acid 62.50mg ) | 1000 Number Pack | 1 | Amoxycillin Trihydrate                             | 8.274 kg                       |
|   |                                                                                                                                                                                                                                                  |                  | 2 | CLAVULANATE POTASSIUM WITH SILICON DIOXIDE 1:1     | 4.6888 kg                      |
|   |                                                                                                                                                                                                                                                  |                  | 3 | SILICONE DIOXIDE(SYLOID 244FP)                     | 3.00 kg                        |
|   |                                                                                                                                                                                                                                                  |                  | 4 | 115CC HDPE BOTTLES 75 ML (250/62.5)                | Relevant as per packing policy |
|   |                                                                                                                                                                                                                                                  |                  | 5 | 28-400 WHITE CLIC LOC CAP WITH PRINTED FSM-1       |                                |
|   |                                                                                                                                                                                                                                                  |                  | 6 | Cap 28/400 WHT CRC W/FS M-I WITH INDUCTION SEALING |                                |

RA concerned may take further necessary action as per above decision of NC.

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 253 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | AUROBINDO PHARMA LTD                        |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002294AM23                  |
| RA File Number               | 09AX04000377 AM23                           |
| Licence No and Date          | 0911003411/27/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 254 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SAINOR LABORATORIES PRIVATE LIMITED         |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002317AM23                  |
| RA File Number               | 09AX04000364 AM23                           |
| Licence No and Date          | 0911003412/28/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|------------------------------|---------------------------------------------|
| Case No.                     | 255 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | SMS PHARMACEUTICALS LIMITED                 |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002320AM23                  |
| RA File Number               | 09AX04000242 AM23                           |
| Licence No and Date          | 0911003415/28/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

|             |                               |
|-------------|-------------------------------|
| Case No.    | 256 / NC/3/MEET/Dec/202223/15 |
| Case Status | Case Approved                 |

| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | SENTISS PHARMA PRIVATE LIMITED                              |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |   |                                                             |               |   |                 |         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|---------------|---------|-----------------|---------|---------|----------------|-----|---------|--------------|-----|---|-----------------------------------------|---------------|---|-----------------|---------|---|-------------------------------------------------------------|---------------|---|-----------------|---------|
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022                 |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |   |                                                             |               |   |                 |         |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | HQRNORM APPLY 00002328AM23                                  |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |   |                                                             |               |   |                 |         |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 05AX04001229 AM23                                           |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |   |                                                             |               |   |                 |         |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 0511014014/28/07/2022                                       |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |   |                                                             |               |   |                 |         |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Dec/202122/12 dated 17/12/2021</b> against advance authorization No. <b>0511003792 dated 23-07-2021</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> <table border="1"> <thead> <tr> <th>Sl. No.</th> <th>Export Product</th> <th>Qty</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Visallergol Eye Drops 0.2 Percent 2.5ml</td> <td>1 Number Vial</td> <td>1</td> <td>Olopatadine HCL</td> <td>5.61 mg</td> </tr> <tr> <td>2</td> <td>Oftahist (Olopatadine Eye Solution 0.1 Percent in 5ml Vial)</td> <td>1 Number Vial</td> <td>2</td> <td>Olopatadine HCL</td> <td>5.61 mg</td> </tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision of NC.</p> |                                                             |               |         |                 |         | Sl. No. | Export Product | Qty | Sl. No. | Import Items | Qty | 1 | Visallergol Eye Drops 0.2 Percent 2.5ml | 1 Number Vial | 1 | Olopatadine HCL | 5.61 mg | 2 | Oftahist (Olopatadine Eye Solution 0.1 Percent in 5ml Vial) | 1 Number Vial | 2 | Olopatadine HCL | 5.61 mg |
| Sl. No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Export Product                                              | Qty           | Sl. No. | Import Items    | Qty     |         |                |     |         |              |     |   |                                         |               |   |                 |         |   |                                                             |               |   |                 |         |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Visallergol Eye Drops 0.2 Percent 2.5ml                     | 1 Number Vial | 1       | Olopatadine HCL | 5.61 mg |         |                |     |         |              |     |   |                                         |               |   |                 |         |   |                                                             |               |   |                 |         |
| 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Oftahist (Olopatadine Eye Solution 0.1 Percent in 5ml Vial) | 1 Number Vial | 2       | Olopatadine HCL | 5.61 mg |         |                |     |         |              |     |   |                                         |               |   |                 |         |   |                                                             |               |   |                 |         |

| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 257 / NC/3/MEET/Dec/202223/15               |         |              |     |  |                |     |         |              |     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------|--------------|-----|--|----------------|-----|---------|--------------|-----|
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Case Approved                               |         |              |     |  |                |     |         |              |     |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | SENTISS PHARMA PRIVATE LIMITED              |         |              |     |  |                |     |         |              |     |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |         |              |     |  |                |     |         |              |     |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | HQRNORM APPLY 00002329AM23                  |         |              |     |  |                |     |         |              |     |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 05AX04001228 AM23                           |         |              |     |  |                |     |         |              |     |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 0511014015/28/07/2022                       |         |              |     |  |                |     |         |              |     |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Jan/202021/4 dated 12.02.2021</b> against advance authorization No. <b>0510413990 dated 13.04.2020</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty</th> </tr> </thead> <tbody> </tbody> </table> |                                             |         |              |     |  | Export Product | Qty | Sl. No. | Import Items | Qty |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Qty                                         | Sl. No. | Import Items | Qty |  |                |     |         |              |     |

|                           |        |   |                    |          |
|---------------------------|--------|---|--------------------|----------|
| Cyclomed Eye Drops 1% 5ml | 1 Pack | 1 | Cyclopentolate HCL | 51.00 mg |
|---------------------------|--------|---|--------------------|----------|

RA concerned may take further necessary action as per above decision of NC.

|                         |                                                    |
|-------------------------|----------------------------------------------------|
| Case No.                | 258 / NC/3/MEET/Dec/202223/15                      |
| Case Status             | Case Approved                                      |
| Party Name              | VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022        |
| HQ File Number          | HQRNORM APPLY 00002334AM23                         |
| RA File Number          | 03AX04002462 AM23                                  |
| Licence No and Date     | 0311016682/28/07/2022                              |

#### Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **8/82-ALC4/2019 dated 20.09.2019** against advance authorization No. **0710114616 dated 04.03.2019**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Sl. No. | Export product                          | Qty.     | Sl. No. | Import items              | Qty.                       |
|---------|-----------------------------------------|----------|---------|---------------------------|----------------------------|
| 1       | CLINDAMYCIN HYDRCHLORIDE 150MG CAPSULES | 1 Number | 1       | CLINDAMYCIN HYDROCHLORIDE | 173.53 mg / 150 mg capsule |
| 2       | CLINDAMYCIN HYDRCHLORIDE 300MG CAPSULES | 1 Number | 1       | CLINDAMYCIN HYDROCHLORIDE | 347.06 mg / 300 mg capsule |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 259 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | DEEPAK PHENOLICS LIMITED                    |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002356AM23                  |
| RA File Number          | 34AX04000402 AM23                           |

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------|--------------|------------|
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                | 3411002585/29/07/2022 |         |              |            |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                          |                       |         |              |            |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>NC/3/MEET/Nov/202223/12 dated 18/11/2022</b> against advance authorization No. <b>3411002081 dated 31/03/2022</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> |                       |         |              |            |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                     | Qty.                  | Sl. No. | Import items | Qty.       |
| Phenol                                                                                                                                                                                                                                                                                                                                                                                                             | 1 MT                  | 1       | Cumene       | 0.84466 MT |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                        |                       |         |              |            |

|                              |                                             |
|------------------------------|---------------------------------------------|
| Case No.                     | 260 / NC/3/MEET/Dec/202223/15               |
| Case Status                  | Case Deferred                               |
| Party Name                   | ALEMBIC PHARMACEUTICALS LIMITED             |
| Meeting Number and Date      | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number               | HQRNORM APPLY 00002358AM23                  |
| RA File Number               | 34AX04000398 AM23                           |
| Licence No and Date          | 3411002586/29/07/2022                       |
| Norms Committee Decision:    |                                             |
| Deferred for comments of TE. |                                             |

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                          | 261 / NC/3/MEET/Dec/202223/15                      |
| Case Status                                                                                                                                                                                                                                                                                                                                                       | Case Approved                                      |
| Party Name                                                                                                                                                                                                                                                                                                                                                        | VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                           | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022        |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                    | HQRNORM APPLY 00002359AM23                         |
| RA File Number                                                                                                                                                                                                                                                                                                                                                    | 03AX04002488 AM23                                  |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                               | 0311016722/29/07/2022                              |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                         |                                                    |
| <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>5/82-ALC4/2018 dated 25.07.2018</b> against advance authorization No. <b>0410163746 dated 29.11.2017</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as</p> |                                                    |

applied by the firm, whichever is less:

| Export product                            | Qty.     | Sl. No. | Import items                | Qty.   |
|-------------------------------------------|----------|---------|-----------------------------|--------|
| AMANTADINE HYDRCHLORIDE<br>100MG CAPSULES | 1 Number | 1       | AMANTADINE<br>HYDROCHLORIDE | 102 mg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 262 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | ZYDUS LIFESCIENCES LIMITED                  |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number          | HQRNORM APPLY 00002362AM23                  |
| RA File Number          | 08AX04000708 AM23                           |
| Licence No and Date     | 0811005658/29/07/2022                       |

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

| Export product                                                                                             | Qty.     | Sl. No. | Import items     | Qty.  |
|------------------------------------------------------------------------------------------------------------|----------|---------|------------------|-------|
| INDOMETHACIN SUPPOSITORIES<br>USP 50 MG((ACTIVE INGREDIENT:<br>INDOMETHACIN USP - NET WT.<br>71.820 KGS.)) | 1 Number | 1       | INDOMETHACIN USP | 51 mg |

RA concerned may take further necessary action as per above decision of NC.

|                         |                                             |
|-------------------------|---------------------------------------------|
| Case No.                | 263 / NC/3/MEET/Dec/202223/15               |
| Case Status             | Case Approved                               |
| Party Name              | STERILE INDIA PRIVATE LIMITED               |
| Meeting Number and Date | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |

| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | HQRNORM APPLY 00002371AM23 |                |                                |         |              |      |                            |      |   |                                |         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------|--------------------------------|---------|--------------|------|----------------------------|------|---|--------------------------------|---------|
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 05AX04001214 AM23          |                |                                |         |              |      |                            |      |   |                                |         |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 0511014036/29/07/2022      |                |                                |         |              |      |                            |      |   |                                |         |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. <b>NC/3/MEET/Dec/202122/12 dated 17/12/2021</b> against advance authorization No. <b>0511003790 dt. 23-07-2021</b>, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>Ceftriaxone Sodium Sterile</td> <td>1 kg</td> <td>1</td> <td>Ceftriaxone Sodium Non Sterile</td> <td>1.04 kg</td> </tr> </tbody> </table> |                            | Export product | Qty.                           | Sl. No. | Import items | Qty. | Ceftriaxone Sodium Sterile | 1 kg | 1 | Ceftriaxone Sodium Non Sterile | 1.04 kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Qty.                       | Sl. No.        | Import items                   | Qty.    |              |      |                            |      |   |                                |         |
| Ceftriaxone Sodium Sterile                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 1 kg                       | 1              | Ceftriaxone Sodium Non Sterile | 1.04 kg |              |      |                            |      |   |                                |         |
| <p>RA concerned may take further necessary action as per above decision of NC.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                            |                |                                |         |              |      |                            |      |   |                                |         |

|                                                                      |                                             |
|----------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                             | 264 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                          | Case Deferred                               |
| Party Name                                                           | ASMEE CHEMICALS PRIVATE LIMITED             |
| Meeting Number and Date                                              | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                       | HQRNORM APPLY 00002335AM23                  |
| RA File Number                                                       | 03AX04002471 AM23                           |
| Licence No and Date                                                  | 0311016692/29/07/2022                       |
| <p>Norms Committee Decision:</p> <p>Deferred for comments of TE.</p> |                                             |

|                                                                      |                                             |
|----------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                             | 265 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                          | Case Deferred                               |
| Party Name                                                           | GUJARAT FLUOROCHEMICALS LIMITED             |
| Meeting Number and Date                                              | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                       | HQRNORM APPLY 00002374AM23                  |
| RA File Number                                                       | 34AX04000340 AM23                           |
| Licence No and Date                                                  | 3411002592/29/07/2022                       |
| <p>Norms Committee Decision:</p> <p>Deferred for comments of TE.</p> |                                             |

| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 266 / NC/3/MEET/Dec/202223/15               |                |                    |         |              |      |                                               |      |   |                    |         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------|--------------------|---------|--------------|------|-----------------------------------------------|------|---|--------------------|---------|
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Case Approved                               |                |                    |         |              |      |                                               |      |   |                    |         |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | INDO AMINES LIMITED                         |                |                    |         |              |      |                                               |      |   |                    |         |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |                |                    |         |              |      |                                               |      |   |                    |         |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | HQRNORM APPLY 00002347AM23                  |                |                    |         |              |      |                                               |      |   |                    |         |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 03AX04002441 AM23                           |                |                    |         |              |      |                                               |      |   |                    |         |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 0311016706/29/07/2022                       |                |                    |         |              |      |                                               |      |   |                    |         |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. <b>5/82-ALC4/2018 dated 25.07.2018</b> against advance authorization No. <b>0310814798 dated 24.07.2017</b>, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:</p> <table border="1"> <thead> <tr> <th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> <tr> <td>Coco Amine or Coco Amine Distilled or IAL CAD</td><td>1 kg</td><td>1</td><td>COCONUT FATTY ACID</td><td>1.02 kg</td></tr> </tbody> </table> <p>RA concerned may take further necessary action as per above decision of NC.</p> |                                             | Export product | Qty.               | Sl. No. | Import items | Qty. | Coco Amine or Coco Amine Distilled or IAL CAD | 1 kg | 1 | COCONUT FATTY ACID | 1.02 kg |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Qty.                                        | Sl. No.        | Import items       | Qty.    |              |      |                                               |      |   |                    |         |
| Coco Amine or Coco Amine Distilled or IAL CAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 1 kg                                        | 1              | COCONUT FATTY ACID | 1.02 kg |              |      |                                               |      |   |                    |         |

|                                                                      |                                             |
|----------------------------------------------------------------------|---------------------------------------------|
| Case No.                                                             | 267 / NC/3/MEET/Dec/202223/15               |
| Case Status                                                          | Case Deferred                               |
| Party Name                                                           | MANGALAM ORGANICS LIMITED                   |
| Meeting Number and Date                                              | NC/ 3/ MEET/ Dec/ 202223/ 15 and 29/12/2022 |
| HQ File Number                                                       | HQRNORM APPLY 00002352AM23                  |
| RA File Number                                                       | 03AX04002033 AM23                           |
| Licence No and Date                                                  | 0311016713/29/07/2022                       |
| <p>Norms Committee Decision:</p> <p>Deferred for comments of TE.</p> |                                             |