



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, CENTRAL DELHI, DELHI, 110011 / वाणिज्य भवन, अकबर रोड, नई दिल्ली

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**(DES - III SECTION)****MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Jun/202324/6**DATED:** 14/06/2023Please 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/Jun/202324/6 dated 14/06/2023 of Norms Committee - III for the year 2023-24 was held on 14/06/2023 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     | T SONGZALIAN, Deputy DGFT                 | DGFT(HQ)   |
| 2     | UTTAM SARKAR, Assistant Section Officer   | DGFT(HQ)   |
| 3     | NAND Lal, Technical Consultant            | DPIIT      |
| 4     | SHAISH KUMAR, Technical Consultant        | DGFT       |
| 5     | DINESHNARAIN MATHUR, Technical Consultant | DGFT       |
| 6     | Nand Lal, Technical Consultant            | DGFT       |

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

|                                                                                                                                                                                                                                                                                                         |                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                | 1 / NC/3/MEET/Jun/202324/6                 |
| Case Status                                                                                                                                                                                                                                                                                             | Case Rejected                              |
| Party Name                                                                                                                                                                                                                                                                                              | AQUILA ORGANICS PRIVATE LIMITED            |
| Meeting Number and Date                                                                                                                                                                                                                                                                                 | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                          | HQRNORM APPLY 00005454AM23                 |
| RA File Number                                                                                                                                                                                                                                                                                          | NA                                         |
| Licence No and Date                                                                                                                                                                                                                                                                                     | 0310830783/null                            |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to <b>reject</b> the case.</p> <p>RA concerned may take further necessary action as per above decision of NC.</p> |                                            |

|                                                                                                                                                                                                                                                                                               |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                      | 2 / NC/3/MEET/Jun/202324/6                 |
| Case Status                                                                                                                                                                                                                                                                                   | Case Approved                              |
| Party Name                                                                                                                                                                                                                                                                                    | ADCOCK INGRAM LIMITED                      |
| Meeting Number and Date                                                                                                                                                                                                                                                                       | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                | HQRNORM APPLY 00005419AM23                 |
| RA File Number                                                                                                                                                                                                                                                                                | NA                                         |
| Licence No and Date                                                                                                                                                                                                                                                                           | 0710104124/15/05/2014                      |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and it was observed that the application of the firm had already been approved in meeting <b>No.6/82/ALC-4/2014 dated 29/08/2014</b>. Hence, the Committee decided to <b>withdraw the application</b></p> |                                            |

|                                                                                                                                                                                                                                         |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                | 3 / NC/3/MEET/Jun/202324/6                 |
| Case Status                                                                                                                                                                                                                             | Case Approved                              |
| Party Name                                                                                                                                                                                                                              | REYAANSH HEALTHCARE                        |
| Meeting Number and Date                                                                                                                                                                                                                 | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                          | HQRNORM REVIW00004873AM23                  |
| RA File Number                                                                                                                                                                                                                          | 039504000872 AM18                          |
| Licence No and Date                                                                                                                                                                                                                     | 0310818545/16/01/2018                      |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.      |
|-----------------------------------------------------------------------------------------------------------------------------------|---------------------|---------|--------------|-----------|
| SELAMECTIN 6% SPOT on 0.25 ML TUBE<br>(Pack Size 3 Tubes x 0.25ML) (NT.WT.0.63<br>KGS 14200 CARTONS (For Veterinary Use<br>only)  | 42600.000<br>Number | 1       | SELAMECTIN   | 7.375 kg. |
| SELAMECTIN 6% SPOT on 0.50 ML TUBE<br>(Pack Size 3 Tubes x 0.50 ML) (NT.WT.1.90<br>KGS 21200 CARTONS (For Veterinary Use<br>only) | 63600.000 Number    |         |              |           |
| SELAMECTIN 6% SPOT on 0.75 ML TUBE<br>(Pack Size 3 Tubes x 0.75 ML) (NT.WT.3.13<br>KGS 23200 CARTONS (For Veterinary Use<br>only) | 69600.000<br>Number |         |              |           |
| SELAMECTIN 6% SPOT on 1 ML TUBE<br>(Pack Size 3 Tubes x 1 ML) (NT.WT.0.44 KGS<br>2475 CARTONS (For Veterinary Use only)           | 7425.000 Number     |         |              |           |
| SELAMECTIN 6% SPOT on 2 ML TUBE<br>(Pack Size 3 Tubes x 2 ML) (NT.WT.1.13 KGS<br>3155 CARTONS (For Veterinary Use only)           | 9465.000 Number     |         |              |           |

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

|                                                                       |                                            |
|-----------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                              | 4 / NC/3/MEET/Jun/202324/6                 |
| Case Status                                                           | Case Deferred                              |
| Party Name                                                            | CROPNOSYS (INDIA) PRIVATE LIMITED          |
| Meeting Number<br>and Date                                            | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                        | HQRNORM REVIW00005535AM23                  |
| RA File Number                                                        | 039404000527 AM19                          |
| Licence No and<br>Date                                                | 0310823957/24/09/2018                      |
| Norms Committee Decision:                                             |                                            |
| <b>The case is under consideration for want for comments from TE.</b> |                                            |

|             |                            |
|-------------|----------------------------|
| Case No.    | 5 / NC/3/MEET/Jun/202324/6 |
| Case Status | Case Approved              |

|                         |                                            |
|-------------------------|--------------------------------------------|
| Party Name              | REYAANSH HEALTHCARE                        |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM REVIW00005644AM23                  |
| RA File Number          | 018205000964 AM20                          |
| Licence No and Date     | 0310833938/06/01/2020                      |

**Norms Committee Decision:**

The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to fix ad-hoc 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.      |
|--------------------------------------------------------------------------------------------------------|-----------------|---------|--------------|-----------|
| SELAMECTIN SIX PERCENT SPOT ON 0.25ML TUBE NET QUANTITY OF SELAMECTIN 1.980 KGS (SELAMECTIN 60 MG/ML)  | 120000.0 CARTON | 1       | SELAMECTIN   | 1.836 kg. |
| SELAMECTIN SIX PERCENT SPOT ON 0.50ML TUBE NET QUANTITY OF SELAMECTIN 6.60 KGS (SELAMECTIN 60 MG/ML)   | 200000.0 CARTON | 2       | SELAMECTIN   | 6.120 kg. |
| SELAMECTIN SIX PERCENT SPOT ON 0.75ML TUBE NET QUANTITY OF SELAMECTIN 7.425 KGS (SELAMECTIN 60 MG/ML)  | 150000.0 CARTON | 3       | SELAMECTIN   | 6.885 kg. |
| SELAMECTIN SIX PERCENT SPOT ON 1 ML TUBE NET QUANTITY OF SELAMECTIN 5.940 KGS<br>(SELAMECTIN 60 MG/ML) | 90000.0 CARTON  | 4       | SELAMECTIN   | 5.508 kg. |
| SELAMECTIN SIX PERCENT SPOT ON 4ML TUBE NET QUANTITY OF SELAMECTIN 2.376 KGS<br>(SELAMECTIN 60 MG/ML)  | 9000.0 CARTON   | 5       | SELAMECTIN   | 2.203 kg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 6 / NC/3/MEET/Jun/202324/6                 |
| Case Status             | Case Deferred                              |
| Party Name              | DELTA FINOCHEM PRIVATE LIMITED             |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM REVIW00003546AM23                  |
| RA File Number          | 039404000112 AM21                          |
| Licence No and          | 0310836419/29/05/2020                      |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |
| <p>Norms Committee Decision:</p> <p>The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm: -</p> <ol style="list-style-type: none"> <li><b>1. Manufacturing process indicating stage wise with justification of 75% yield.</b></li> <li><b>2. Start the reaction with liquid Bromine and Hexamine and Iso Propyle Alcohol giving molecular height of reactants and products.</b></li> <li><b>3. Also submit one shipping bill of the export product along with export and import product statement of the said Authorization.</b></li> </ol> |  |

| Case No.                                                                                                                                                                                                                                                                                                                                  | 7 / NC/3/MEET/Jun/202324/6                 |         |                               |           |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------|-------------------------------|-----------|----------------|------|---------|--------------|------|---------------------------------------|-------|---|-------------------------------|-----------|---|----------------|-----------|
| Case Status                                                                                                                                                                                                                                                                                                                               | Case Approved                              |         |                               |           |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |
| Party Name                                                                                                                                                                                                                                                                                                                                | DELTA FINOCHEM PRIVATE LIMITED             |         |                               |           |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                   | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |         |                               |           |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |
| HQ File Number                                                                                                                                                                                                                                                                                                                            | HQRNORM APPLY 00000298AM23                 |         |                               |           |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |
| RA File Number                                                                                                                                                                                                                                                                                                                            | 03AX04002053 AM22                          |         |                               |           |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                       | 0311013980/19/04/2022                      |         |                               |           |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                 |                                            |         |                               |           |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |
| The Committee considered the case as per agenda and it was decided to fix ad-hoc 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 rowspan="2">N-Cetyl Bromide (1- Bromo Hexadecane)</td><td rowspan="2">1 kg.</td><td>1</td><td>Ecorol 16/99P (Cetyl Alcohol)</td><td>0.835 kg.</td></tr><tr><td>2</td><td>Liquid Bromine</td><td>0.276 kg.</td></tr></table> |                                            |         |                               |           | Export Product | Qty. | Sl. No. | Import Items | Qty. | N-Cetyl Bromide (1- Bromo Hexadecane) | 1 kg. | 1 | Ecorol 16/99P (Cetyl Alcohol) | 0.835 kg. | 2 | Liquid Bromine | 0.276 kg. |
| Export Product                                                                                                                                                                                                                                                                                                                            | Qty.                                       | Sl. No. | Import Items                  | Qty.      |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |
| N-Cetyl Bromide (1- Bromo Hexadecane)                                                                                                                                                                                                                                                                                                     | 1 kg.                                      | 1       | Ecorol 16/99P (Cetyl Alcohol) | 0.835 kg. |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |
|                                                                                                                                                                                                                                                                                                                                           |                                            | 2       | Liquid Bromine                | 0.276 kg. |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                               |                                            |         |                               |           |                |      |         |              |      |                                       |       |   |                               |           |   |                |           |

|                         |                                            |  |  |  |
|-------------------------|--------------------------------------------|--|--|--|
| Case No.                | 8 / NC/3/MEET/Jun/202324/6                 |  |  |  |
| Case Status             | Case Approved                              |  |  |  |
| Party Name              | REYAANSH HEALTHCARE                        |  |  |  |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |  |  |  |
| HQ File Number          | HQRNORM APPLY 00001972AM23                 |  |  |  |
| RA File Number          | 03AX04002163 AM23                          |  |  |  |
| Licence No and Date     | 0311016269/11/07/2022                      |  |  |  |

## Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.(in gm) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---------|--------------|-------------|
| IMPACT SOLUTION FOR CATS 0.40 ML.(Packing 3 Tubes X 0.40 ml) (IMPACT SOLUTION FOR CATS 0.40 ML. Each ml contains Imidacloprid 100 mg + Moxidectin 10 mg. Moxidectin consumed including wastages & overages :- 0.224 Kgs) | 51000.0<br>Number | 1       | Moxidectin   | 208.08      |
| IMPACT SOLUTION FOR CATS 0.80 ML.(Packing 3 Tubes X 0.80 ml)(IMPACT SOLUTION FOR CATS 0.80 ML. Each ml contains Imidacloprid 100 mg + Moxidectin 10 mg. Moxidectin consumed including wastages & overages :- 0.528 Kgs.) | 60000.0<br>Number | 2       | Moxidectin   | 489.60      |
| IMPACT SOLUTION FOR DOGS 0.40 ML.(Packing 3 Tubes X 0.40 ml )(IMPACT SOLUTION FOR DOGS 0.40 ML. Each ml contains Imidacloprid 100 mg + Moxidectin 25 mg. Moxidectin consumed including wastages & overages :- 0.594 Kgs) | 54000.0<br>Number | 3       | Moxidectin   | 550.80      |
| IMPACT SOLUTION FOR DOGS 1 ML.(Packing 3 Tubes X 1 ml )(IMPACT SOLUTION FOR DOGS 1 ML. Each ml contains Imidacloprid 100 mg + Moxidectin 25 mg. Moxidectin consumed including wastages & overages :- 1.650 Kgs)          | 60000.0<br>Number | 4       | Moxidectin   | 1530.00     |
| IMPACT SOLUTION FOR DOGS 4 ML.(Packing 3 Tubes X 4 ml )(IMPACT SOLUTION FOR DOGS 4 ML. Each ml contains Imidacloprid 100 mg + Moxidectin 25 mg. Moxidectin consumed including wastages & overages :- 1.980 Kgs)          | 18000.0<br>Number | 5       | Moxidectin   | 1836.00     |
| IMPACT SOLUTION FOR DOGS 2.5 ML.(Packing 3 Tubes X 2.5 ML )(IMPACT SOLUTION FOR DOGS 2.5 ML. Each ml contains Imidacloprid 100 mgs + Moxidectin 25 mg. Moxidectin consumed including wastages & overage 1.031 Kgs)       | 15000.0<br>Number | 6       | Moxidectin   | 956.33      |

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

|             |                            |
|-------------|----------------------------|
| Case No.    | 9 / NC/3/MEET/Jun/202324/6 |
| Case Status | Case Approved              |

|                         |                                            |
|-------------------------|--------------------------------------------|
| Party Name              | REYAANSH HEALTHCARE                        |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00004021AM23                 |
| RA File Number          | 03AX04003763 AM23                          |
| Licence No and Date     | 0311018994/02/11/2022                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.<br>(in kg.) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|---------|--------------|------------------|
| Selamectin 6% Spot On 0.25 ml Tube. Each ml Contains Selamectin 60 mg(Net Quantity of Selamectin Consumed Including Wastages & Overages : 1.299 Kg.(Net Content of Selamectin is 1.181 kg).)   | 78720.0<br>Number  | 1       | SELAMECTIN   | 1.299            |
| Selamectin 6% Spot On 0.50 ml Tube. Each ml Contains Selamectin 60 mg(Net Quantity of Selamectin Consumed Including Wastages & Overages : 5.271 Kg. (Net Content of Selamectin is 4.792 kg.))  | 159720.0<br>Number | 2       | SELAMECTIN   | 5.271            |
| Selamectin 6% Spot On 0.75 ml Tube. Each ml Contains Selamectin 60 mg(Net Quantity of Selamectin Consumed Including Wastages & Overages : 10.247 Kg. (Net Content of Selamectin is 9.315 kg).) | 207000.0<br>Number | 3       | SELAMECTIN   | 10.247           |
| Selamectin 6% Spot On 1 ml Tube. Each ml Contains Selamectin 60 mg(Net Quantity of Selamectin Consumed Including Wastages & Overages : 5.306 Kg. (Net Content of Selamectin is 4.824 kg).)     | 80400.0<br>Number  | 4       | SELAMECTIN   | 5.306            |
| Selamectin 6% Spot On 2 ml Tube. Each ml Contains Selamectin 60 mg(Net Quantity of Selamectin Consumed Including Wastages & Overages : 4.435 Kg. (Net Content of Selamectin is 4.032 kg).)     | 33600.0<br>Number  | 5       | SELAMECTIN   | 4.113            |
| Selamectin 6% Spot On 4 ml Tube. Each ml Contains Selamectin 60 mg(Net Quantity of Selamectin Consumed Including Wastages & Overages : 3.453 Kg.(Net Content of Selamectin is 3.139 kg.))      | 13080.0<br>Number  | 6       | SELAMECTIN   | 3.453            |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 10 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | REYAANSH HEALTHCARE                        |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00004769AM23                 |
| RA File Number          | 03AX04004317 AM23                          |
| Licence No and Date     | 0311019713/02/12/2022                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|--------------------------------|-------------|
| Maropitant Injection 10 mg / ml(Each ml contains: Maropitant Citrate 14.484 mg. Equivalent to Maropitant 10 mg. Pack Size: 20 ml. Total Maropitant Citrate Consumed along with wastages & overages - 1 Kg.) | 1 Number | 1       | Maropitant Citrate Monohydrate | 304.135 mg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 11 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | EMCURE PHARMACEUTICALS LIMITED             |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006566AM23                 |
| RA File Number          | NA                                         |
| Licence No and Date     | 3111001908/23/12/2022                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. 15/82-ALC4/2018** dated **22/03/2019** against advance authorization **No.3110067194** dated **10/10/2018**, it was decided to fix ad-hoc 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.                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------|-----------------------|------------------------------|
| CIPROBIOTIC FORTE TAB 500MG<br>(CIPROFLOXACIN TABLETS<br>500MG)(EACH FILM COATED<br>TABLET CONTAIN :<br>CIPROFLOXACIN<br>HYDROCHLORIDE USP<br>EQUIVALENT TO CIPROFLOXACIN<br>500 MG [NET WEIGHT 4300 KG]) | One 500 mg.<br>tablet | 1       | CIPROFLOXACIN HCL USP | 555.0 mg./ 500<br>mg. Tablet |

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

|                            |                                            |
|----------------------------|--------------------------------------------|
| Case No.                   | 12 / NC/3/MEET/Jun/202324/6                |
| Case Status                | Case Approved                              |
| Party Name                 | MERIDIAN ENTERPRISES PRIVATE LIMITED       |
| Meeting Number<br>and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number             | HQRNORM APPLY 00005783AM23                 |
| RA File Number             | 03AX04004956 AM23                          |
| Licence No and<br>Date     | 0311020765/17/01/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. **NC/3/MEET/Nov/202223/12** dated **18/11/2022** against advance authorization No. **0311013150** dated **21/03/2022**, it was decided to fix ad-hoc 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.       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|----------------------|------------|
| Dequalinium Chloride Oral Spray (Dequadin Oral Spray) 25 ML Bottle. (Each ml contains: Dequalinium Chloride 0.5 percent(Dequalinium Chloride Oral Spray (Dequadin Oral Spray) 25 ML Bottle. (Each ml contains: Dequalinium Chloride 0.5 percent (net content of Input per ml=5mg,Net content per 25ml bottle = 125mg Total net content = 3.2353 kgs)) | 1 Number | 1       | Dequalinium Chloride | 127.50 mg. |

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

|                                                                                                                                                                                                                                               |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                      | 13 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                   | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                    | SHARON BIO-MEDICINE LIMITED                |
| Meeting Number and Date                                                                                                                                                                                                                       | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                | HQRNORM APPLY 00005790AM23                 |
| RA File Number                                                                                                                                                                                                                                | 03AX04005196 AM23                          |
| Licence No and Date                                                                                                                                                                                                                           | 0311020778/18/01/2023                      |
| Norms Committee Decision:                                                                                                                                                                                                                     |                                            |
| <b>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.</b> |                                            |

| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 14 / NC/3/MEET/Jun/202324/6                |                |                      |                       |              |      |                                                                                                                                                                                                                                                                                                                                                       |          |   |                      |                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------|----------------------|-----------------------|--------------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|----------------------|-----------------------|
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Case Approved                              |                |                      |                       |              |      |                                                                                                                                                                                                                                                                                                                                                       |          |   |                      |                       |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | MERIDIAN ENTERPRISES PRIVATE LIMITED       |                |                      |                       |              |      |                                                                                                                                                                                                                                                                                                                                                       |          |   |                      |                       |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |                |                      |                       |              |      |                                                                                                                                                                                                                                                                                                                                                       |          |   |                      |                       |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | HQRNORM APPLY 00005789AM23                 |                |                      |                       |              |      |                                                                                                                                                                                                                                                                                                                                                       |          |   |                      |                       |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 03AX04004961 AM23                          |                |                      |                       |              |      |                                                                                                                                                                                                                                                                                                                                                       |          |   |                      |                       |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 0311020771/18/01/2023                      |                |                      |                       |              |      |                                                                                                                                                                                                                                                                                                                                                       |          |   |                      |                       |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                            |                |                      |                       |              |      |                                                                                                                                                                                                                                                                                                                                                       |          |   |                      |                       |
| The Committee considered the case as per agenda and it was decided to fix ad-hoc 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>Dequalinium Chloride Oral Spray (Dequadin Oral Spray) 25 ML Bottle. (Each ml contains: Dequalinium Chloride 0.5 percent(Dequalinium Chloride Oral Spray (Dequadin Oral Spray) 25 ML Bottle. (Each ml contains: Dequalinium Chloride 0.5 percent (net content of Input per ml=5mg,Net content per 25ml bottle = 125mg Total net content = 3.2353 kgs))</td><td>1 Number</td><td>1</td><td>Dequalinium Chloride</td><td>126.90 mg. per Bottle</td></tr></table> |                                            | Export Product | Qty.                 | Sl. No.               | Import Items | Qty. | Dequalinium Chloride Oral Spray (Dequadin Oral Spray) 25 ML Bottle. (Each ml contains: Dequalinium Chloride 0.5 percent(Dequalinium Chloride Oral Spray (Dequadin Oral Spray) 25 ML Bottle. (Each ml contains: Dequalinium Chloride 0.5 percent (net content of Input per ml=5mg,Net content per 25ml bottle = 125mg Total net content = 3.2353 kgs)) | 1 Number | 1 | Dequalinium Chloride | 126.90 mg. per Bottle |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Qty.                                       | Sl. No.        | Import Items         | Qty.                  |              |      |                                                                                                                                                                                                                                                                                                                                                       |          |   |                      |                       |
| Dequalinium Chloride Oral Spray (Dequadin Oral Spray) 25 ML Bottle. (Each ml contains: Dequalinium Chloride 0.5 percent(Dequalinium Chloride Oral Spray (Dequadin Oral Spray) 25 ML Bottle. (Each ml contains: Dequalinium Chloride 0.5 percent (net content of Input per ml=5mg,Net content per 25ml bottle = 125mg Total net content = 3.2353 kgs))                                                                                                                                                                                                                       | 1 Number                                   | 1              | Dequalinium Chloride | 126.90 mg. per Bottle |              |      |                                                                                                                                                                                                                                                                                                                                                       |          |   |                      |                       |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 15 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | ROYAL PHARMA                               |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00005811AM23                 |
| RA File Number          | 03AX04005198 AM23                          |
| Licence No and Date     | 0311020795/19/01/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Dec/202223/15** dated **29/12/2022** against advance authorization **No.0311015473** dated **13/06/2022**, it was decided to fix ad-hoc 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.      |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------|---------|-----------------------------------------------------------|-----------|
| BICALUTAMIDE SULFIDE(CHEMICAL NAME: N-[4-CYANO-3-(TRIFLUORO METHYL)PHENYL]-3-[(4- FLUOROPHENYL THIO)] -2-HYDROXY-2-METHYL PROPIONALIDE) | 1 kg. | 1       | N - [4-CYANO-3- (TRIFLUORO METHYL) PHENYL] METHACRYLAMIDE | 0.709 kg. |
|                                                                                                                                         |       | 2       | 4- FLUOROTHIOPHENOL                                       | 0.30 kg.  |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 16 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | SUVEN PHARMACEUTICALS LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006169AM23                 |
| RA File Number          | 09AX04000957 AM23                          |
| Licence No and Date     | 0911004428/08/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Mar/202223/24** dated **13/04/2023** against advance authorization **No.0911002860** dated **19/04/2022** , it was decided to fix ad-hoc 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.      |
|---------------------------------------------------|-------|---------|-------------------------|-----------|
| 1,2,3,5-Tetra-O-acetyl-B-L- Ribofuranose (POWDER) | 1 kg. | 1       | METHYL ISO BUTYL KETONE | 1.840 kg. |
|                                                   |       | 2       | L RIBOSE                | 0.842 kg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 17 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | ALTA LABORATORIES LIMITED                  |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006166AM23                 |
| RA File Number          | 03AX04005444 AM23                          |
| Licence No and Date     | 0311021244/08/02/2023                      |

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Nov/202223/12** dated **18/11/2022** against advance authorization **No. 5211002509** dated **19/05/2022**, it was decided to fix ad-hoc 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.     |
|--------------------------------|-------|---------|--------------------------|----------|
| METHYL PARABEN(METHYL PARABEN) | 1 kg. | 1       | PARAHYDROXY 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.    | 18 / NC/3/MEET/Jun/202324/6 |
| Case Status | Case Approved               |
| Party Name  | REYAANSH HEALTHCARE         |

| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |         |              |           |                |      |         |              |      |                                                                                                                                                                                         |             |   |            |           |                                                                                                                                                                                          |             |   |            |           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------|--------------|-----------|----------------|------|---------|--------------|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---|------------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---|------------|-----------|
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | HQRNORM APPLY 00006176AM23                 |         |              |           |                |      |         |              |      |                                                                                                                                                                                         |             |   |            |           |                                                                                                                                                                                          |             |   |            |           |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 03AX04005439 AM23                          |         |              |           |                |      |         |              |      |                                                                                                                                                                                         |             |   |            |           |                                                                                                                                                                                          |             |   |            |           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 0311021258/08/02/2023                      |         |              |           |                |      |         |              |      |                                                                                                                                                                                         |             |   |            |           |                                                                                                                                                                                          |             |   |            |           |
| <b>Norms Committee Decision:</b><br><br>The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting <b>No. NC/3/MEET/Sep/202223/9</b> dated <b>07/10/2022</b> against advance authorization <b>No. 0311011529</b> dated <b>18/02/2022</b> , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-                                                                                                                                                                                                                                                                              |                                            |         |              |           |                |      |         |              |      |                                                                                                                                                                                         |             |   |            |           |                                                                                                                                                                                          |             |   |            |           |
| <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>SELAMECTIN 6% SPOT ON 0.25 ML TUBE(Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed Including Wastages &amp; Overages : 1.100 Kg. (Net Content of Selamectin is 1 kg))</td> <td>100 Numbers</td> <td>1</td> <td>SELAMECTIN</td> <td>1.53 gram</td> </tr> <tr> <td>SELAMECTIN 6% SPOT ON 0.75 ML TUBE(Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed Including Wastages &amp; Overages : 1 Kg. (Net content of Selamectin is 0.9099 kg))</td> <td>100 Numbers</td> <td>1</td> <td>SELAMECTIN</td> <td>4.59 gram</td> </tr> </tbody> </table> |                                            |         |              |           | Export Product | Qty. | Sl. No. | Import Items | Qty. | SELAMECTIN 6% SPOT ON 0.25 ML TUBE(Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed Including Wastages & Overages : 1.100 Kg. (Net Content of Selamectin is 1 kg)) | 100 Numbers | 1 | SELAMECTIN | 1.53 gram | SELAMECTIN 6% SPOT ON 0.75 ML TUBE(Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed Including Wastages & Overages : 1 Kg. (Net content of Selamectin is 0.9099 kg)) | 100 Numbers | 1 | SELAMECTIN | 4.59 gram |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Qty.                                       | Sl. No. | Import Items | Qty.      |                |      |         |              |      |                                                                                                                                                                                         |             |   |            |           |                                                                                                                                                                                          |             |   |            |           |
| SELAMECTIN 6% SPOT ON 0.25 ML TUBE(Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed Including Wastages & Overages : 1.100 Kg. (Net Content of Selamectin is 1 kg))                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 100 Numbers                                | 1       | SELAMECTIN   | 1.53 gram |                |      |         |              |      |                                                                                                                                                                                         |             |   |            |           |                                                                                                                                                                                          |             |   |            |           |
| SELAMECTIN 6% SPOT ON 0.75 ML TUBE(Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed Including Wastages & Overages : 1 Kg. (Net content of Selamectin is 0.9099 kg))                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 100 Numbers                                | 1       | SELAMECTIN   | 4.59 gram |                |      |         |              |      |                                                                                                                                                                                         |             |   |            |           |                                                                                                                                                                                          |             |   |            |           |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                            |         |              |           |                |      |         |              |      |                                                                                                                                                                                         |             |   |            |           |                                                                                                                                                                                          |             |   |            |           |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 19 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Case Approved                              |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                             | OPTIMUS DRUGS PRIVATE LIMITED              |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                         | HQRNORM APPLY 00006206AM23                 |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 09AX04001006 AM23                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 0911004437/09/02/2023                      |
| <b>Norms Committee Decision:</b><br><br>The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting <b>No. NC/3/MEET/Jan/202223/18</b> dated <b>23/01/2023</b> against advance authorization <b>No. 0911003684</b> dated <b>23/09/2022</b> , it was decided to fix ad-hoc 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 (S)-4-oxo-4,6,7,8-tetrahydropyrrolo [1,2-a]pyrimidine-6-carboxylate((Pyrimidinone acid, sodium salt)) | 1 kg | 1       | L Pyroglutamic Acid        | 2.70 kg    |
|                                                                                                              |      | 2       | Triethyl Amine             | 2.27 kg    |
|                                                                                                              |      | 3       | 2,5-Norbornadiene          | 1.73 kg    |
|                                                                                                              |      | 4       | Chloro Sulfonyl Isocyanate | 2.778 kg   |
|                                                                                                              |      | 5       | Isopropyl Alcohol          | 4.02 kg    |
|                                                                                                              |      | 6       | Methyl Tert Butyl Ether    | 5.91 kg    |
|                                                                                                              |      | 7       | Toluene                    | 5.72 Litre |
|                                                                                                              |      | 8       | Ethyl Acetate              | 2.95 Litre |
|                                                                                                              |      | 9       | N-Heptane                  | 1.82 kg    |
|                                                                                                              |      | 10      | Ethyl Benzene              | 1.00 kg    |
|                                                                                                              |      | 11      | Methanol                   | 1.50 kg    |
|                                                                                                              |      | 12      | Methylene Chloride         | 3.25 Litre |

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

|                           |                                            |
|---------------------------|--------------------------------------------|
| Case No.                  | 20 / NC/3/MEET/Jun/202324/6                |
| Case Status               | Case Approved                              |
| Party Name                | JUBILANT INGREVIA LIMITED                  |
| Meeting Number and Date   | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number            | HQRNORM APPLY 00006211AM23                 |
| RA File Number            | 05AX04003224 AM23                          |
| Licence No and Date       | 0511017283/09/02/2023                      |
| Norms Committee Decision: |                                            |

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/May/202324/5** dated **08/06/2023** against advance authorization **No.0511013507** dated **30/06/2022**, it was decided to fix ad-hoc 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.      |
|------------------------------|-------|---------|-----------------|-----------|
| Choline Chloride 60% Aqueous | 1 kg. | 1       | Ethylene Oxide  | 0.197 kg. |
|                              |       | 2       | Trimethyl Amine | 0.261 kg. |

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

|                                                                                                                                                                                                                                        |                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                               | 21 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                            | Case Deferred                              |
| Party Name                                                                                                                                                                                                                             | GLENMARK PHARMACEUTICALS LIMITED           |
| Meeting Number and Date                                                                                                                                                                                                                | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                         | HQRNORM APPLY 00006186AM23                 |
| RA File Number                                                                                                                                                                                                                         | 03AX04005398 AM23                          |
| Licence No and Date                                                                                                                                                                                                                    | 0311021275/09/02/2023                      |
| Norms Committee Decision:                                                                                                                                                                                                              |                                            |
| Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case. |                                            |

|                                                                                                                                                                                                |                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                       | 22 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                    | Case Approved                              |
| Party Name                                                                                                                                                                                     | ADCOCK INGRAM LIMITED                      |
| Meeting Number and Date                                                                                                                                                                        | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                 | HQRNORM APPLY 00006192AM23                 |
| RA File Number                                                                                                                                                                                 | 07AX04001687 AM23                          |
| Licence No and Date                                                                                                                                                                            | 0711006394/09/02/2023                      |
| Norms Committee Decision:                                                                                                                                                                      |                                            |
| The Committee considered the case as per agenda and it was decided to fix ad-hoc 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(PYRIDOSTIGMINE BROMIDE 10mg+LACTOSE MONOHYDRATE-30mg Tablets (MESTINON 10mg Tablets, PYRIDOSTIGMINE 30.00 KGS+LACTOSE 90.00 KGS, No of Tabs 3000000) PH.EUR) | 1<br>NumberTablet | 1       | PYRIDOSTIGMINE BROMIDE PH.EUR              | 10.2 mg.  |
|                                                                                                                                                                |                   | 2       | LACTOSE MONOHYDRATE-PHARMATOSE 350M PH.EUR | 30.00 mg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 23 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | DHANUKA LABORATORIES LIMITED               |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006204AM23                 |
| RA File Number          | 05AX04003209 AM23                          |
| Licence No and Date     | 0511017281/09/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. **NC/3/MEET/Apr/202324/1** dated **28/04/2023** against advance authorization **No.0511016533** dated **26/12/2022**, it was decided to fix ad-hoc 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. (in kg.) |
|-----------------------|-------|---------|-------------------------------------|---------------|
| CEFTIBUTEN JP(POWDER) | 1 kg. | 1       | Pencillin G Potassium First Crystal | 8.515         |
|                       |       | 2       | METHYLENE CHLORIDE /Dichloromethane | 76.165        |
|                       |       | 3       | Triethylamine                       | 3.214         |
|                       |       | 4       | Methanol                            | 41.137        |

|  |  |    |                            |       |
|--|--|----|----------------------------|-------|
|  |  | 5  | Ethyl-4-chloroacetoacetate | 1.82  |
|  |  | 6  | Methyl-3-methoxy acrylate  | 1.62  |
|  |  | 7  | Prenol                     | 3.114 |
|  |  | 8  | N,N-Dimethyl Formamide     | 12.16 |
|  |  | 9  | Acetonitrile               | 7.50  |
|  |  | 10 | Activated carbon           | 0.200 |
|  |  | 11 | Acetone                    | 1.20  |
|  |  | 12 | Toluene                    | 23.00 |
|  |  | 13 | Acetic acid                | 5.50  |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 24 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | MANKIND PHARMA LIMITED                     |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006194AM23                 |
| RA File Number          | 05AX04003232 AM23                          |
| Licence No and Date     | 0511017272/09/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.      |
|------------------------------------------|-----------|---------|--------------|-----------|
| DOXEPIN HYDROCHLORIDE CAPSULES USP 10 MG | 6400000.0 | 1       | DOXEPIN HCL  | 72.66 kg. |

|                                           |                      |   |             |           |
|-------------------------------------------|----------------------|---|-------------|-----------|
|                                           | Numbers              |   |             |           |
| DOXEPIN HYDROCHLORIDE CAPSULES USP 25 MG  | 3200000.0<br>Numbers | 2 | DOXEPIN HCL | 90.83 kg. |
| DOXEPIN HYDROCHLORIDE CAPSULES USP 50 MG  | 1500000.0<br>Numbers | 3 | DOXEPIN HCL | 85.15 kg. |
| DOXEPIN HYDROCHLORIDE CAPSULES USP 75 MG  | 1300000.0<br>Numbers | 4 | DOXEPIN HCL | 110.7 kg. |
| DOXEPIN HYDROCHLORIDE CAPSULES USP 100 MG | 1300000.0<br>Numbers | 5 | DOXEPIN HCL | 147.6 kg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 25 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | INTAS PHARMACEUTICALS LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006238AM23                 |
| RA File Number          | 08AX04001875 AM23                          |
| Licence No and Date     | 0811007267/10/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. 4/82-ALC4/2019** dated **19/07/2019** against advance authorization **No.0810142125 dated 08/03/2018**, it was decided to fix ad-hoc 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.                |
|-------------------------------------------------------------------------------------------------|----------|---------|----------------------------------------------|---------------------|
| SPIRONOLACTONE TABLETS BP 25 MG(EACH FILM COATED TABLET CONTAINS: SPIRONOLACTONE PH.EUR. 25 MG) | 1 Number | 1       | SPIRONOLACTONE EP / BP / IP / USP / PH. EUR. | 25.50 mg per Tablet |
| SPIRONOLACTONE TABLETS BP 50 MG(EACH FILM COATED TABLET CONTAINS: SPIRONOLACTONE                | 1 Number | 2       | SPIRONOLACTONE EP / BP / IP / USP / PH. EUR. | 51.00 mg per Tablet |

|                                                                                                                                                                           |          |   |                                              |                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|----------------------------------------------|----------------------|
| PH.EUR. 50 MG)                                                                                                                                                            |          |   |                                              |                      |
| SPIRONOLACTONE TABLETS BP 100 MG(EACH FILM COATED TABLET CONTAINS: SPIRONOLACTONE<br><br>PH.EUR. 100 MG [IN WHICH ACTIVE INGREDIENT SPIRONOLACTONE USED IS 116.250 KGS.]) | 1 Number | 3 | SPIRONOLACTONE EP / BP / IP / USP / PH. EUR. | 102.00 mg per tablet |

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

|                                                                                                                                                                                                |                                            |  |  |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--|--|--|
| Case No.                                                                                                                                                                                       | 26 / NC/3/MEET/Jun/202324/6                |  |  |  |
| Case Status                                                                                                                                                                                    | Case Approved                              |  |  |  |
| Party Name                                                                                                                                                                                     | CLAROID PHARMACEUTICALS PRIVATE LIMITED    |  |  |  |
| Meeting Number and Date                                                                                                                                                                        | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |  |  |  |
| HQ File Number                                                                                                                                                                                 | HQRNORM APPLY 00006241AM23                 |  |  |  |
| RA File Number                                                                                                                                                                                 | 08AX04001837 AM23                          |  |  |  |
| Licence No and Date                                                                                                                                                                            | 0811007268/10/02/2023                      |  |  |  |
| Norms Committee Decision:                                                                                                                                                                      |                                            |  |  |  |
| The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.    | 27 / NC/3/MEET/Jun/202324/6   |  |  |  |
| Case Status | Case Approved                 |  |  |  |
| Party Name  | INTAS PHARMACEUTICALS LIMITED |  |  |  |

|                         |                                            |
|-------------------------|--------------------------------------------|
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006243AM23                 |
| RA File Number          | 08AX04001877 AM23                          |
| Licence No and Date     | 0811007279/10/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. 4/82-ALC4/2019** dated **19/07/2019** against advance authorization **No.0810142125 dated 08/03/2018**, it was decided to fix ad-hoc 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.                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|----------------------------------------------|----------------------|
| SPIRONOLACTONE TABLETS BP 25 MG(EACH FILM COATED TABLET CONTAINS: SPIRONOLACTONE PH.EUR. 25 MG)                                                                    | 1 Number | 1       | SPIRONOLACTONE EP / BP / IP / USP / PH. EUR. | 25.50 mg per Tablet  |
| SPIRONOLACTONE TABLETS BP 50 MG(EACH FILM COATED TABLET CONTAINS: SPIRONOLACTONE PH.EUR. 50 MG)                                                                    | 1 Number | 2       | SPIRONOLACTONE EP / BP / IP / USP / PH. EUR. | 51.00 mg per Tablet  |
| SPIRONOLACTONE TABLETS BP 100 MG(EACH FILM COATED TABLET CONTAINS: SPIRONOLACTONE PH.EUR. 100 MG [IN WHICH ACTIVE INGREDIENT SPIRONOLACTONE USED IS 116.250 KGS.]) | 1 Number | 3       | SPIRONOLACTONE EP / BP / IP / USP / PH. EUR. | 102.00 mg per tablet |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 28 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | INTAS PHARMACEUTICALS LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006244AM23                 |
| RA File Number          | 08AX04001874 AM23                          |
| Licence No and Date     | 0811007285/10/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|----------------------------------------------------------|------------|
| HYDROXYCHLOROQUINE SULFATE TABLETS USP 100 MG(EACH FILM COATED TABLET CONTAINS:<br><br>HYDROXYCHLOROQUINE SULFATE USP 100MG EQ. TO HYDROXYCHLOROQUINE 77.5 MG)                           | 1 Number | 1       | HYDROXYCHLOROQUINE SULFATE EP / BP / IP / USP / PH. EUR. | 102.00 mg. |
| HYDROXYCHLOROQUINE SULFATE TABLETS USP 200 MG(EACH FILM COATED TABLET CONTAINS:<br><br>HYDROXYCHLOROQUINE SULFATE USP 200MG EQ. TO HYDROXYCHLOROQUINE 155 MG)                            | 1 Number | 2       | HYDROXYCHLOROQUINE SULFATE EP / BP / IP / USP / PH. EUR. | 204.00 mg. |
| HYDROXYCHLOROQUINE SULFATE TABLETS USP 300 MG(EACH FILM COATED TABLET CONTAINS:<br><br>HYDROXYCHLOROQUINE SULFATE USP 300MG EQ. TO HYDROXYCHLOROQUINE 232.50 mg)                         | 1 Number | 3       | HYDROXYCHLOROQUINE SULFATE EP / BP / IP / USP / PH. EUR. | 306.00 mg. |
| HYDROXYCHLOROQUINE SULFATE TABLETS USP 400 MG(EACH FILM COATED TABLET CONTAINS:<br><br>HYDROXYCHLOROQUINE SULFATE USP 400MG EQ. TO HYDROXYCHLOROQUINE 310 MG [IN WHICH ACTIVE INGREDIENT | 1 Number | 4       | HYDROXYCHLOROQUINE SULFATE EP / BP / IP / USP / PH. EUR. | 408.00 mg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 29 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Deferred                              |
| Party Name              | AUORE LIFE SCIENCES PRIVATE LIMITED        |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006267AM23                 |
| RA File Number          | 09AX04000893 AM23                          |

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Licence No and Date                                                                                                                                                                                                                                                            | 0911004453/13/02/2023 |
| <p>Norms Committee Decision:</p> <p>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.</p> |                       |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 30 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | PIRAMAL PHARMA LIMITED                     |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | HQRNORM APPLY 00006286AM23                 |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 03AX04005525 AM23                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 0311021390/13/02/2023                      |
| <p>Norms Committee Decision:</p> <p>The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm: -</p> <ol style="list-style-type: none"> <li>1. No import quantity is available on Portal.</li> <li>2. Firm is advised to furnish hard copy of application along with Advance Authorisation.</li> </ol> <p>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.</p> |                                            |

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| Case No.                                                                                                                                                                                       | 31 / NC/3/MEET/Jun/202324/6                |  |  |  |
| Case Status                                                                                                                                                                                    | Case Approved                              |  |  |  |
| Party Name                                                                                                                                                                                     | GLAND PHARMA LTD                           |  |  |  |
| Meeting Number and Date                                                                                                                                                                        | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |  |  |  |
| HQ File Number                                                                                                                                                                                 | HQRNORM APPLY 00006277AM23                 |  |  |  |
| RA File Number                                                                                                                                                                                 | 09AX04000920 AM23                          |  |  |  |
| Licence No and Date                                                                                                                                                                            | 0911004455/13/02/2023                      |  |  |  |
| Norms Committee Decision:                                                                                                                                                                      |                                            |  |  |  |
| The Committee considered the case as per agenda and it was decided to fix ad-hoc 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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| Bottle(USP Condition: The firm should account for 6.00 Kgs of input at SL No.1 of the import list in the resultant product which should be reflected in SBs.) |  |  |  |  |
| RA concerned may take further necessary action as per above decision of NC                                                                                    |  |  |  |  |

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|-------------------------|--------------------------------------------|
| Case No.                | 32 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | GLAND PHARMA LTD                           |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006276AM23                 |
| RA File Number          | 09AX04000967 AM23                          |
| Licence No and Date     | 0911004454/13/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------|------------------|-----------------|
| Diazepam Injection USP, 5mg/ml 2ml fill in 2.25ml Pre-filled Syringe (USP Condition: The firm should account for 2.084 Kgs of input at SL No.1 and 208,350 Nos each of input at SL No. 2,3,4 of the import list in the resultant product should be reflected in SBs.) | 208350.0 Number | 1       | Diazepam         | 2.292 kg.       |
|                                                                                                                                                                                                                                                                       |                 | 2       | Barrel Syringes  | 219476.0 Number |
|                                                                                                                                                                                                                                                                       |                 | 3       | Plunger Stoppers | 231081.1 Number |
|                                                                                                                                                                                                                                                                       |                 | 4       | Plunger Rods     | 214475.0 Number |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 33 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Deferred                              |
| Party Name              | KOPRAN LIMITED                             |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |

|                                                                                                                                                                                                                                        |                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| HQ File Number                                                                                                                                                                                                                         | HQRNORM APPLY 00006275AM23 |
| RA File Number                                                                                                                                                                                                                         | 03AX04005476 AM23          |
| Licence No and Date                                                                                                                                                                                                                    | 0311021384/13/02/2023      |
| Norms Committee Decision:                                                                                                                                                                                                              |                            |
| Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case. |                            |

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 34 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | HETERO LABS LIMITED                        |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006266AM23                 |
| RA File Number          | 09AX04000928 AM23                          |
| Licence No and Date     | 0911004452/13/02/2023                      |

## Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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. (in kg.) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------|---------|------------------------------------------------------|---------------|
| ( R)-9-[2-phosphonomethoxy]propyl] Adenine<br>(?Compounds containing a pyrimidine ring (whether or not hydrogenated) or piperazine ring in the structure) | 1 kg. | 1       | ADENINE                                              | 1.06          |
|                                                                                                                                                           |       | 2       | N,N-DIMETHYLFORMAMIDE                                | 2.00          |
|                                                                                                                                                           |       | 3       | (R)-1,2-PROPYLENE CARBONATE                          | 0.98          |
|                                                                                                                                                           |       | 4       | N-METHYL-2-PYRROLIDONE                               | 0.21          |
|                                                                                                                                                           |       | 5       | Diethyl Para Toluene Sulfonyl Oxy Methyl Phosphonate | 1.00          |
|                                                                                                                                                           |       | 6       | Magnesium Tert. Butoxide                             | 1.00          |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 35 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | KOPRAN LIMITED                             |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006261AM23                 |
| RA File Number          | 03AX04005485 AM23                          |
| Licence No and Date     | 0311021362/13/02/2023                      |

#### Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Apr/202324/1** dated **28/04/2023** against advance authorization **No.0311020258** dated **26/12/2022**, it was decided to fix ad-hoc 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.                            |
|------------------------|-------|---------|----------------------------|---------------------------------|
| CEFEPIME FOR INJECTION | 1 kg. | 1       | CEFEPIME HCL (NON-STERILE) | 0.655 kg.                       |
|                        |       | 2       | L-ARGININE                 | 0.370 kg.                       |
|                        |       | 3       | PACKING MATERIAL           | Relevant as per packing policy. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 36 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Deferred                              |
| Party Name              | KOPRAN LIMITED                             |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006260AM23                 |
| RA File Number          | 03AX04005475 AM23                          |
| Licence No and Date     | 0311021361/13/02/2023                      |

#### Norms Committee Decision:

The committee considered the request of firm for fixation of ad-hoc norms and it was observed that review case of the firm for same export item against the Advance Authorisation No. 0311004745 dated 19/06/2021 is already under consideration. Hence, the committee decided to defer the case till the finalization of review case.

|          |                             |
|----------|-----------------------------|
| Case No. | 37 / NC/3/MEET/Jun/202324/6 |
|----------|-----------------------------|

| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                   | Case Approved                              |                |                   |           |              |      |                                                 |       |   |               |          |   |                   |           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------|-------------------|-----------|--------------|------|-------------------------------------------------|-------|---|---------------|----------|---|-------------------|-----------|
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                    | YASHO INDUSTRIES LIMITED                   |                |                   |           |              |      |                                                 |       |   |               |          |   |                   |           |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                       | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |                |                   |           |              |      |                                                 |       |   |               |          |   |                   |           |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                | HQRNORM APPLY 00006314AM23                 |                |                   |           |              |      |                                                 |       |   |               |          |   |                   |           |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                | 03AX04005523 AM23                          |                |                   |           |              |      |                                                 |       |   |               |          |   |                   |           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                           | 0311021434/14/02/2023                      |                |                   |           |              |      |                                                 |       |   |               |          |   |                   |           |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                                     |                                            |                |                   |           |              |      |                                                 |       |   |               |          |   |                   |           |
| The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. <b>NC/3/MEET/Apr/202324/1</b> dated <b>28/04/2023</b> against advance authorization No. <b>0311019863</b> dated <b>08/12/2022</b> , it was decided to fix ad-hoc 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 rowspan="2">TETRA BENZYL THIURAM DISULFIDE (QUREACC TBZTD )</td><td rowspan="2">1 kg.</td><td>1</td><td>DIBENZYLAMINE</td><td>0.74 kg.</td></tr><tr><td>2</td><td>CARBON DISULPHIDE</td><td>0.285 kg.</td></tr></table>                                                                                         |                                            | Export Product | Qty.              | Sl. No.   | Import Items | Qty. | TETRA BENZYL THIURAM DISULFIDE (QUREACC TBZTD ) | 1 kg. | 1 | DIBENZYLAMINE | 0.74 kg. | 2 | CARBON DISULPHIDE | 0.285 kg. |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                                                | Qty.                                       | Sl. No.        | Import Items      | Qty.      |              |      |                                                 |       |   |               |          |   |                   |           |
| TETRA BENZYL THIURAM DISULFIDE (QUREACC TBZTD )                                                                                                                                                                                                                                                                                                                                                                               | 1 kg.                                      | 1              | DIBENZYLAMINE     | 0.74 kg.  |              |      |                                                 |       |   |               |          |   |                   |           |
|                                                                                                                                                                                                                                                                                                                                                                                                                               |                                            | 2              | CARBON DISULPHIDE | 0.285 kg. |              |      |                                                 |       |   |               |          |   |                   |           |
| RA concerned may take further action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                                             |                                            |                |                   |           |              |      |                                                 |       |   |               |          |   |                   |           |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                          | 38 / NC/3/MEET/Jun/202324/6                |         |              |      |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                       | Case Approved                              |         |              |      |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                        | SENTISS PHARMA PRIVATE LIMITED             |         |              |      |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                           | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |         |              |      |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                    | HQRNORM APPLY 00006299AM23                 |         |              |      |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                    | 05AX04003061 AM23                          |         |              |      |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                               | 0511017317/14/02/2023                      |         |              |      |
| 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/Jan/202223/18</b> dated <b>23/01/2023</b> against advance authorization No. <b>0511014706 dated 07/09/2022</b> , it was decided to fix adhocs 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. |

|                            |        |   |                |         |
|----------------------------|--------|---|----------------|---------|
| Inokain Eye Drops 0.4% 5ml | 1 Vial | 1 | Benoxinate HCL | 20.4 mg |
|----------------------------|--------|---|----------------|---------|

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 39 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | AMNEAL INJECTABLES PRIVATE LIMITED         |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006333AM23                 |
| RA File Number          | 08AX04001899 AM23                          |
| Licence No and Date     | 0811007309/15/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---------|---------------------------|-------------|
| NOREPINEPHRINE BITARTRATE INJECTION USP, 1 mg/ml (4ml)<br>(NOREPINEPHRINE BITARTRATE INJECTION USP, 1 mg/ml (4ml)<br>(i.e.1.887 mg equal to Norepinephrine 1 mg)) | 100 Vials | 1       | NOREPINEPHRINE BITARTRATE | 911.872 mg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 40 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Deferred                              |
| Party Name              | ARCH PROTECTION CHEMICALS PRIVATE LIMITED  |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006341AM23                 |
| RA File Number          | 03AX04004385 AM23                          |
| Licence No and Date     | 0311021465/15/02/2023                      |

**Norms Committee Decision:**

The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm: -

1. **Chemistry giving molecular weight of reactant & product giving calculation as yield of the reaction with justification.**
2. **Production / Consumption data duly certified by CA.**
3. **The value of by product, if any, formed in the process.**

**Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.**

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 41 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Deferred                              |
| Party Name              | BELCHEM INDUSTRIES (INDIA) PVT LTD         |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006352AM23                 |
| RA File Number          | 03AX04005586 AM23                          |
| Licence No and Date     | 0311021482/16/02/2023                      |

Norms Committee Decision:

The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm: -

1. **Justification for lower yield of 74%.**
2. **Production/Consumption data duly certified by CA.**

**Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.**

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 42 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Deferred                              |
| Party Name              | ENCUBE ETHICALS PRIVATE LIMITED            |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006351AM23                 |
| RA File Number          | 03AX04005363 AM23                          |
| Licence No and Date     | 0311021477/16/02/2023                      |

Norms Committee Decision:

**Under consideration for physical verification.**

|             |                             |
|-------------|-----------------------------|
| Case No.    | 43 / NC/3/MEET/Jun/202324/6 |
| Case Status | Case Approved               |

|                         |                                            |
|-------------------------|--------------------------------------------|
| Party Name              | J B CHEMICALS AND PHARMACEUTICALS LIMITED  |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006347AM23                 |
| RA File Number          | 03AX04005511 AM23                          |
| Licence No and Date     | 0311021471/16/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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. allowed in gm. |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------|---------------------------|---------------------|
| 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) 30.822 Kgs (ii) 13.664 Kgs (iii) 26568.481 Kgs.) | 1000 Number | 1       | Benzylamine Hydrochloride | 3.06                |
|                                                                                                                                                                                                                                                                                                                                  |             | 2       | Cetylpyridinium Chloride  | 1.33                |
|                                                                                                                                                                                                                                                                                                                                  |             | 3       | Isomalt ST-M              | 2586                |
| 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) 23.973 Kgs. (ii) 20664.374 Kgs.)                                     | 1000 Number | 4       | Benzylamine Hydrochloride | 3.06                |
|                                                                                                                                                                                                                                                                                                                                  |             | 5       | Isomalt ST-M              | 2586                |
| 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) 3826.059 Kg.)                                                                               | 1000 Number | 6       | Benzylamine Hydrochloride | 3.06                |
|                                                                                                                                                                                                                                                                                                                                  |             | 7       | Isomalt ST-M              | 2586                |
| Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.                                                                                                                                                                                                                     | 1000 Number | 8       | Cetylpyridinium Chloride  | 1.00                |

|                                                                                                                                                                                                                          |             |    |                          |      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|----|--------------------------|------|
| (Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 1.968 Kg (ii) 3826.059 Kg.)                                                                                    |             | 9  | Isomalt ST-M             | 2586 |
| 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) 1.352 Kg (ii) 3496.272 Kg ) | 1000 Number | 10 | Cetylpyridinium Chloride | 1.00 |
|                                                                                                                                                                                                                          |             | 11 | Isomalt ST-M             | 2586 |

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

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 44 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | R.L.FINE CHEM PRIVATE LIMITED              |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | HQRNORM APPLY 00006391AM23                 |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 07AX04001706 AM23                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 0711006466/17/02/2023                      |
| <p>Norms Committee Decision:</p> <p>The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-</p> <p><b>1. Complete technical details as per Annexure to appendix-4E.</b></p> <p><b>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case</b></p> |                                            |

|                           |                                            |
|---------------------------|--------------------------------------------|
| Case No.                  | 45 / NC/3/MEET/Jun/202324/6                |
| Case Status               | Case Deferred                              |
| Party Name                | SALICYLATES & CHEMICALS PRIVATE LIMITED    |
| Meeting Number and Date   | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number            | HQRNORM APPLY 00006402AM23                 |
| RA File Number            | 09AX04001018 AM23                          |
| Licence No and Date       | 0911004488/17/02/2023                      |
| Norms Committee Decision: |                                            |

The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-

- i. Step wise manufacturing process.
- ii. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.
- iii. Complete technical details as per Annexure to Appendix 4E for chemical products.
- iv. Stoichiometric balance between import and export on molar basis.
- v. Details of indigenous input with quantity.
- vi. Sample of shipping bills and bill of entry of the import and export products along with statement of Input-Output as per export documents of said authorization.

**Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.**

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 46 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | SUN PHARMACEUTICAL INDUSTRIES LIMITED      |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006405AM23                 |
| RA File Number          | 05AX04003274 AM23                          |
| Licence No and Date     | 0511017389/17/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET Mar/202223/22** dated **24/03/2023** against advance authorization **No.0511015798** dated **14/11/2022** , it was decided to fix ad-hoc 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 Capsules 250 mg (Each capsule contains Amoxycillin Trihydrate equivalent to 250 mg of Amoxycillin) ((Equivalent to 250.000Kg of bulk drug))  | 1000000 Numbers | 1       | Amoxycillin Trihydrate | 292.68 kg. |
| Amoxycillin Capsules 500 mg (Each capsule contains Amoxycillin Trihydrate equivalent to 500 mg of Amoxycillin) ((Equivalent to 500.000 Kg of bulk drug)) | 1000000 Numbers | 2       | Amoxycillin Trihydrate | 585.36 kg. |

|                                                                                                                                                                                                                                                                                                                                                                                   |                  |   |                                                           |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---|-----------------------------------------------------------|--------------|
| Amoxycillin Tablets 1000 mg (Each tablet contains Amoxycillin Trihydrate equivalent to 1000 mg of Amoxycillin) ((Equivalent to 1000.000Kg of bulk drug))                                                                                                                                                                                                                          | 1000000 Numbers  | 3 | Amoxycillin Trihydrate                                    | 1170.72 kg.  |
| Amoxycillin Trihydrate & Clavulanate Potassium + Microcrystalline Cellulose 1:1 Tablets/Capsules 375 mg((Each Tablet/Capsule contains Amoxycillin Trihydrate equivalent to Amoxycillin 250mg andClavulanate Potassium + Microcrystalline Cellulose (1:1) equivalent to Clavulanic acid 125mg) (Equivalent to 2050 Kg of Amoxycillin Trihydrate and 1025 Kg Clavula)               | 8200000 Numbers  | 4 | Amoxycillin Trihydrate                                    | 2399.64 kg.  |
|                                                                                                                                                                                                                                                                                                                                                                                   |                  | 5 | Clavulanate Potassium + Microcrystallin e Cellulose (1:1) | 2490.94 kg.  |
| Amoxycillin Trihydrate and Clavulanate Potassium + Microcrystalline Cellulose 1:1 Tablets/Capsules 625 mg((Each Tablet/Capsule contains Amoxycillin Trihydrate equivalent to Amoxycillin 500mg and Clavulanate Potassium + Microcrystalline Cellulose (1:1) equivalent to Clavulanic acid 125mg) (Equivalent to 10500 Kg of Amoxycillin Trihydrate and 2625 Kg Clav)              | 21000000 Numbers | 6 | Amoxycillin Trihydrate                                    | 12290.86 kg. |
|                                                                                                                                                                                                                                                                                                                                                                                   |                  | 7 | Clavulanate Potassium + Microcrystallin e Cellulose (1:1) | 6379.23 kg.  |
| Amoxycillin Trihydrate and Clavulanate Potassium + Microcrystalline Cellulose 1:1 Tablets/Capsules 1000 mg (Each Tablet/(Capsule contains Amoxycillin Trihydrate equi. to Amoxycillin 875mg & Clavulanate Potassium + Microcrystalline Cellulose (1:1) equi. to Clavulanic acid 125mg) (Equi. to 20300.000Kg of Amoxycillin Trihydrate and 2900.000Kg of Clavulanate Potassium +) | 23200000 Numbers | 8 | Amoxycillin Trihydrate                                    | 23762.32 kg. |
|                                                                                                                                                                                                                                                                                                                                                                                   |                  | 9 | Clavulanate Potassium + Microcrystallin e Cellulose (1:1) | 7047.53 kg.  |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 47 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | CIPLA LIMITED                              |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006408AM23                 |
| RA File Number          | 03AX04005479 AM23                          |
| Licence No and          | 0311021534/17/02/2023                      |

Date

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------|---------------------------|------------|
| Testosterone Topical Solution 30 / 1.5mg / ml Pack Size 110ml(Each Actuation delivers : Testosterone USP 30mg Also contains Alcohol USP ?. Approx. 49.55% w/v (QS to 100% w/v)) | 48000.0 Numbers | 1       | Testosterone USP          | 91.2 kg.   |
|                                                                                                                                                                                 |                 | 2       | Alcohol (Ethanol 95% v/v) | 2616.0 kg. |

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

|                                                                                                                                                                                                                                               |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                      | 48 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                   | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                    | ABBOTT HEALTHCARE PRIVATE LIMITED          |
| Meeting Number and Date                                                                                                                                                                                                                       | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                | HQRNORM APPLY 00006441AM23                 |
| RA File Number                                                                                                                                                                                                                                | 03AX04005543 AM23                          |
| Licence No and Date                                                                                                                                                                                                                           | 0311021564/20/02/2023                      |
| Norms Committee Decision:                                                                                                                                                                                                                     |                                            |
| <b>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.</b> |                                            |

|                           |                                            |
|---------------------------|--------------------------------------------|
| Case No.                  | 49 / NC/3/MEET/Jun/202324/6                |
| Case Status               | Case Approved                              |
| Party Name                | RUMIT LIFE CARE                            |
| Meeting Number and Date   | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number            | HQRNORM APPLY 00006465AM23                 |
| RA File Number            | 03AX04005602 AM23                          |
| Licence No and Date       | 0311021579/20/02/2023                      |
| Norms Committee Decision: |                                            |

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Apr/202324/1 dated 28/04/2023** against advance authorization **No. 0311020160 dated 20/12/2022**, it was decided to fix ad-hoc 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.      |
|-----------------------------------------|-------|---------|----------------------------|-----------|
| Betamethasone Dipropionate IP/BP/EP/USP | 1 kg. | 1       | Betamethasone IP/BP/EP/USP | 0.868 kg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 50 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | SOLARA ACTIVE PHARMA SCIENCES LIMITED      |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006459AM23                 |
| RA File Number          | 04AX04000974 AM23                          |
| Licence No and Date     | 0411004919/20/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Apr/202324/1 dated 28/04/2023** against advance authorization **No. 0411004581 dated 07/12/2022**, it was decided to fix ad-hoc 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.      |
|----------------|-------|---------|------------------------|-----------|
| IBUPROFEN      | 1 kg. | 1       | Isobutyl Acetophenone  | 1.11 kg.  |
|                |       | 2       | Sodium Metal           | 0.235 kg. |
|                |       | 3       | Monochloro Acetic Acid | 0.919 kg. |
|                |       | 4       | Isopropyl Alcohol      | 0.50 kg.  |

|  |  |   |                   |           |
|--|--|---|-------------------|-----------|
|  |  | 5 | Sodium Dichromate | 0.630 kg. |
|--|--|---|-------------------|-----------|

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 51 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | SOLARA ACTIVE PHARMA SCIENCES LIMITED      |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006458AM23                 |
| RA File Number          | 04AX04001010 AM23                          |
| Licence No and Date     | 0411004918/20/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Apr/202324/1 dated 28/04/2023** against advance authorization **No. 0411004581 dated 07/12/2022**, it was decided to fix ad-hoc 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.      |
|----------------|-------|---------|------------------------|-----------|
| IBUPROFEN      | 1 kg. | 1       | Isobutyl Acetophenone  | 1.11 kg.  |
|                |       | 2       | Sodium Metal           | 0.235 kg. |
|                |       | 3       | Monochloro Acetic Acid | 0.919 kg. |
|                |       | 4       | Isopropyl Alcohol      | 0.50 kg.  |
|                |       | 5       | Sodium Dichromate      | 0.630 kg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 52 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | J B CHEMICALS AND PHARMACEUTICALS LIMITED  |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |

|                     |                            |
|---------------------|----------------------------|
| HQ File Number      | HQRNORM APPLY 00006428AM23 |
| RA File Number      | 03AX04005553 AM23          |
| Licence No and Date | 0311021549/20/02/2023      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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. allowed in gm. |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------|---------------------------|---------------------|
| Benzylamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and (allother flavours. Each lozenge contains (i) Benzylamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride- 1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 30.822 Kgs (ii) 13.664 Kgs (iii) 26568.481 Kgs.) | 1000 Number | 1       | Benzylamine Hydrochloride | 3.06                |
|                                                                                                                                                                                                                                                                                                                                 |             | 2       | Cetylpyridinium Chloride  | 1.33                |
|                                                                                                                                                                                                                                                                                                                                 |             | 3       | Isomalt ST-M              | 2586                |
| Benzylamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-BacterialLozengesSugarFree.Eachlozengecontains(i)BenzylamineHydrochloride -3mg(ii)IsomaltST-M-2586mg.Netcontent(i) 23.973 Kgs. (ii) 20664.374 Kgs.)                                                      | 1000 Number | 4       | Benzylamine Hydrochloride | 3.06                |
|                                                                                                                                                                                                                                                                                                                                 |             | 5       | Isomalt ST-M              | 2586                |
| 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) 3826.059 Kg.)                                                                              | 1000 Number | 6       | Benzylamine Hydrochloride | 3.06                |
|                                                                                                                                                                                                                                                                                                                                 |             | 7       | Isomalt ST-M              | 2586                |
| 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) 3826.059 Kg.)                                                                              | 1000 Number | 8       | Cetylpyridinium Chloride  | 1.00                |
|                                                                                                                                                                                                                                                                                                                                 |             |         |                           |                     |
|                                                                                                                                                                                                                                                                                                                                 |             | 9       | Isomalt ST-M              | 2586                |

|                                                                                                                                                                                                                          |             |    |                          |      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|----|--------------------------|------|
| 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) 1.352 Kg (ii) 3496.272 Kg ) | 1000 Number | 10 | Cetylpyridinium Chloride | 1.00 |
|                                                                                                                                                                                                                          |             | 11 | Isomalt ST-M             | 2586 |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 53 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | J B CHEMICALS AND PHARMACEUTICALS LIMITED  |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006427AM23                 |
| RA File Number          | 03AX04005554 AM23                          |
| Licence No and Date     | 0311021548/20/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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. allowed in gm. |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------|---------------------------|---------------------|
| Benzydamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and (allother flavours. Each lozenge contains (i) Benzydamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride- 1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 30.822 Kgs (ii) 13.664 Kgs (iii) 26568.481 Kgs.) | 1000 Number | 1       | Benzydamine Hydrochloride | 3.06                |
|                                                                                                                                                                                                                                                                                                                                 |             | 2       | Cetylpyridinium Chloride  | 1.33                |
|                                                                                                                                                                                                                                                                                                                                 |             | 3       | Isomalt ST-M              | 2586                |
| Benzydamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-BacterialLozengesSugarFree.Eachlozengecontains(i)BenzydamineHydrochloride -3mg(ii)IsomaltST-M-2586mg.Netcontent(i) 23.973 Kgs. (ii) 20664.374 Kgs.)                                                      | 1000 Number | 4       | Benzydamine Hydrochloride | 3.06                |
|                                                                                                                                                                                                                                                                                                                                 |             | 5       | Isomalt ST-M              | 2586                |
| 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) 3826.059 Kg.)                                                                              | 1000 Number | 6       | Benzydamine Hydrochloride | 3.06                |
|                                                                                                                                                                                                                                                                                                                                 |             | 7       | Isomalt ST-M              | 2586                |

|                                                                                                                                                                                                                                                    |             |    |                          |      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|----|--------------------------|------|
| 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) 3826.059 Kg.) | 1000 Number | 8  | Cetylpyridinium Chloride | 1.00 |
|                                                                                                                                                                                                                                                    |             | 9  | Isomalt ST-M             | 2586 |
| 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) 1.352 Kg (ii) 3496.272 Kg )                           | 1000 Number | 10 | Cetylpyridinium Chloride | 1.00 |
|                                                                                                                                                                                                                                                    |             | 11 | Isomalt ST-M             | 2586 |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 54 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | J B CHEMICALS AND PHARMACEUTICALS LIMITED  |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006426AM23                 |
| RA File Number          | 03AX04005589 AM23                          |
| Licence No and Date     | 0311021547/20/02/2023                      |

**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/20202223/12 dated 18/11/2022** against advance authorization No. **03110014993 dated 25/05/2022**, it was decided to fix 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       | Cetylpyridinium Chloride, Benzydamine Hydrochloride and Pholcodine Lozenges Sugar Free Blackcurrant/ Pineapple & Lime/(Honey, Lemon & Ginger/Other Flavours. Each Lozenge contains (i) Pholcodine 5.50mg (ii) Benzydamine Hydrochloride 1.50 mg (iii) Cetylpyridinium Chloride 1.33 mg (iv)Isomalt ST-M 2583 mg. Net Content (i) 43.80 kg (ii) 11.94 kg (iii) 10.59 kg (iv) 20568 Kg) | 1 Number | 1       | Pholcodine                | 5.61 mg   |
|         |                                                                                                                                                                                                                                                                                                                                                                                       |          | 2       | Benzydamine Hydrochloride | 1.53mg    |
|         |                                                                                                                                                                                                                                                                                                                                                                                       |          | 3       | Cetylpyridinium Chloride  | 1.357 mg  |
|         |                                                                                                                                                                                                                                                                                                                                                                                       |          | 4       | Isomalt ST-M              | 2583.0 mg |

|   |                                                                                                                                                                                                                                                                                                                          |          |   |                          |           |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|--------------------------|-----------|
| 2 | Pholcodine and Cetylpyridinium Chloride Lozenges Sugar Free Orange / Lemon and Other Flavours. Each Lozenge contains (i) Pholcodine 5.50 mg (ii) Cetylpyridinium Chloride 1.33 mg (iii) Isomalt ST-M 2579 mg. Net Content (i) Pholcodine-30.77 kg (ii) Cetylpyridinium Chloride-7.44 kg (iii) Isomalt ST-M-14427.96 kg.) | 1 Number | 5 | Pholcodine               | 5.61 mg   |
|   |                                                                                                                                                                                                                                                                                                                          |          | 6 | Cetylpyridinium Chloride | 1.357 mg  |
|   |                                                                                                                                                                                                                                                                                                                          |          | 7 | Isomalt ST-M             | 2579.0 mg |

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

|                                                                                                                                                                                                                                               |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                      | 55 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                   | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                    | AUORE LIFE SCIENCES PRIVATE LIMITED        |
| Meeting Number and Date                                                                                                                                                                                                                       | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                | HQRNORM APPLY 00006487AM23                 |
| RA File Number                                                                                                                                                                                                                                | 09AX04001024 AM23                          |
| Licence No and Date                                                                                                                                                                                                                           | 0911004510/21/02/2023                      |
| Norms Committee Decision:                                                                                                                                                                                                                     |                                            |
| <b>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.</b> |                                            |

|                                                                                                                                                                                                |                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                       | 56 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                    | Case Approved                              |
| Party Name                                                                                                                                                                                     | ALEMBIC PHARMACEUTICALS LIMITED            |
| Meeting Number and Date                                                                                                                                                                        | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                 | HQRNORM APPLY 00006518AM23                 |
| RA File Number                                                                                                                                                                                 | 34AX04001067 AM23                          |
| Licence No and Date                                                                                                                                                                            | 3411003416/22/02/2023                      |
| Norms Committee Decision:                                                                                                                                                                      |                                            |
| The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.                       |
|--------------------------------------------------------------------------------------------------------------------------------|----------|---------|------------------|----------------------------|
| Fluorouracil Injection USP 2.5 gm 50 ML(Fluorouracil Injection USP 2.5 gm 50 ML (Net content of active ingredients 65.00 kgs ) | 1 Number | 1       | Fluorouracil USP | 2.60 gm / 50 ml Injection  |
| Fluorouracil Injection USP 5 gm 100 ML(Fluorouracil Injection USP 5 gm 100 ML (Net content of active ingredients 240.00 kgs)   | 1 Number | 2       | Fluorouracil USP | 5.20 gm / 100 ml Injection |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 57 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | ALEMBIC PHARMACEUTICALS LIMITED            |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006517AM23                 |
| RA File Number          | 34AX04001068 AM23                          |
| Licence No and Date     | 3411003415/22/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.                       |
|--------------------------------------------------------------------------------------------------------------------------------|----------|---------|------------------|----------------------------|
| Fluorouracil Injection USP 2.5 gm 50 ML (Fluorouracil Injection USP 2.5 gm 50 ML (Net content of active ingredients 65.00 kgs) | 1 Number | 1       | Fluorouracil USP | 2.60 gm / 50 ml Injection  |
| Fluorouracil Injection USP 5 gm 100 ML (Fluorouracil Injection USP 5 gm 100 ML (Net content of active ingredients 240.00 kgs)  | 1 Number | 2       | Fluorouracil USP | 5.20 gm / 100 ml Injection |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 58 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | TORRENT PHARMACEUTICALS LTD                |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006564AM23                 |
| RA File Number          | 08AX04001906 AM23                          |
| Licence No and Date     | 0811007374/23/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|--------------|---------------------------|
| CLOZAPINE TABLETS (CLOZAPYL 25MG) (ZIPROC 25MG)(EACH UNCOATED TABLET CONTAINS:CLOZAPINE BP 25 MG NET CONTENT OF CLOZAPINE BP SHOULD NOT BE LESS THAN 18.750 KGS. IN EXPORT ITEM) | 1 Number | 1       | CLOZAPINE BP | 25.50 mg / 25 mg. Tablet  |
| CLOZAPINE TABLETS (ZIPROC 100MG)(EACH UNCOATED TABLET CONTAINS: CLOZAPINE BP 100 MGNET CONTENT OF CLOZAPINE BP SHOULD NOT BE LESS THAN 520.000 KGS. IN EXPORT ITEM)              | 1 Number | 2       | CLOZAPINE BP | 102.0 mg / 100 mg. tablet |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 59 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | INTAS PHARMACEUTICALS LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006524AM23                 |
| RA File Number          | 08AX04001944 AM23                          |
| Licence No and Date     | 0811007355/23/02/2023                      |

## Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|----------------------------------------------------------------|------------|
| HYDROXYCHLOROQUINE SULFATE<br>TABLETS USP 100 MG(EACH FILM<br>COATED TABLET CONTAINS:<br><br>HYDROXYCHLOROQUINE SULFATE USP<br>100MG EQ. TO HYDROXYCHLOROQUINE<br>(77.5 MG)                          | 1 Number | 1       | HYDROXYCHLOROQUINE<br>SULFATE EP / BP / IP / USP / PH.<br>EUR. | 102.00 mg. |
| HYDROXYCHLOROQUINE SULFATE<br>TABLETS USP 200 MG(EACH FILM<br>COATED TABLET CONTAINS:<br><br>HYDROXYCHLOROQUINE SULFATE USP<br>200MG EQ. TO HYDROXYCHLOROQUINE<br>(155 MG)                           | 1 Number | 2       | HYDROXYCHLOROQUINE<br>SULFATE EP / BP / IP / USP / PH.<br>EUR. | 204.00 mg. |
| HYDROXYCHLOROQUINE SULFATE<br>TABLETS USP 300 MG(EACH FILM<br>COATED TABLET CONTAINS:<br><br>HYDROXYCHLOROQUINE SULFATE USP<br>300MG EQ. TO HYDROXYCHLOROQUINE<br>(232.50 mg)                        | 1 Number | 3       | HYDROXYCHLOROQUINE<br>SULFATE EP / BP / IP / USP / PH.<br>EUR. | 306.00 mg. |
| HYDROXYCHLOROQUINE SULFATE<br>TABLETS USP 400 MG(EACH FILM<br>COATED TABLET CONTAINS:<br><br>HYDROXYCHLOROQUINE SULFATE USP<br>400MG EQ. TO HYDROXYCHLOROQUINE<br>310 MG [IN WHICH ACTIVE INGREDIENT | 1 Number | 4       | HYDROXYCHLOROQUINE<br>SULFATE EP / BP / IP / USP / PH.<br>EUR. | 408.00 mg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 60 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | HONOUR LAB LIMITED                         |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006534AM23                 |

|                                                                                                                                                                                                |                       |         |                                                                    |               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------|--------------------------------------------------------------------|---------------|
| RA File Number                                                                                                                                                                                 | 09AX04000902 AM23     |         |                                                                    |               |
| Licence No and Date                                                                                                                                                                            | 0911004499/23/02/2023 |         |                                                                    |               |
| Norms Committee Decision:                                                                                                                                                                      |                       |         |                                                                    |               |
| The Committee considered the case as per agenda and it was decided to fix ad-hoc 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. (in kg.) |
| (2R-cis)-5-(4-amino-1,2-dihydro-2-oxo-1-pyrimidinyl)-1,3-oxathiolane-2-carboxylic acid(2S,5R)-methyl ester.(Otherheterocyclic compounds)                                                       | 1 kg.                 | 1       | 5-Hydroxy-1,3-oxathiolane-2-carboxylicacid(1R,2S,5R) menthyl ester | 1.00          |
|                                                                                                                                                                                                |                       | 2       | Dimethyl formamide                                                 | 0.2632        |
|                                                                                                                                                                                                |                       | 3       | Triphosgene                                                        | 0.421         |
|                                                                                                                                                                                                |                       | 4       | Cytosine                                                           | 0.375         |
|                                                                                                                                                                                                |                       | 5       | Hexamethyl disilazane                                              | 0.660         |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                    |                       |         |                                                                    |               |

|                                                                                                                                                                                                                                                                                                                                                                                                                               |                                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                      | 61 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                   | Case Approved                              |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                    | INTAS PHARMACEUTICALS LIMITED              |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                       | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                | HQRNORM APPLY 00006526AM23                 |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                | 08AX04001943 AM23                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                           | 0811007356/23/02/2023                      |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                                     |                                            |
| The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting <b>No.NC/3/MEET/Apr/20202324/1</b> dated <b>28/04/2023</b> against advance authorization <b>No.0811006675</b> dated <b>07/12/2022</b> , it was decided to fix ad-hoc 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.             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|-------------------------------------------------------|------------------|
| NALTREXONE HYDROCHLORIDE TABLETS USP 50 MG(EACH UNCOATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE USP 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 308.505 KGS.]) | 1 Number | 1       | NALTREXONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR | 51.93 mg/ tablet |

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

|                                                                                                                                                                                                                                                                                                                                                                                                         |                                            |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------------|---------|-----------------|---------|---------|----------------|-----|---------|--------------|-----|---|-----------------------------------------|---------------|---|-----------------|---------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                | 62 / NC/3/MEET/Jun/202324/6                |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                             | Case Approved                              |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                              | SENTISS PHARMA PRIVATE LIMITED             |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                 | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                          | HQRNORM APPLY 00006587AM23                 |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                          | 05AX04003315 AM23                          |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                     | 0511017491/24/02/2023                      |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |
| 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/Dec/202223/15 dated 29/12/2022</b> against advance authorization <b>No.0511014014dated 28/07/2022</b> , it was decided to fix 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>Sl. No.</td><td>Export Product</td><td>Qty</td><td>Sl. No.</td><td>Import Items</td><td>Qty</td></tr><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></table>                                                                                                                                 |                                            |               |         |                 |         | 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 |
| 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 |         |                |     |         |              |     |   |                                         |               |   |                 |         |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                             |                                            |               |         |                 |         |         |                |     |         |              |     |   |                                         |               |   |                 |         |

|                         |                                            |  |  |  |  |
|-------------------------|--------------------------------------------|--|--|--|--|
| Case No.                | 63 / NC/3/MEET/Jun/202324/6                |  |  |  |  |
| Case Status             | Case Approved                              |  |  |  |  |
| Party Name              | SANOFI INDIA LIMITED                       |  |  |  |  |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |  |  |  |  |

| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | HQRNORM APPLY 00006589AM23                                                                                                     |                 |         |              |           |         |                |      |         |              |      |   |                                                                                                                                |                 |   |            |           |   |                                                                                                                    |                 |   |            |           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|-----------------|---------|--------------|-----------|---------|----------------|------|---------|--------------|------|---|--------------------------------------------------------------------------------------------------------------------------------|-----------------|---|------------|-----------|---|--------------------------------------------------------------------------------------------------------------------|-----------------|---|------------|-----------|
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 03AX04005778 AM23                                                                                                              |                 |         |              |           |         |                |      |         |              |      |   |                                                                                                                                |                 |   |            |           |   |                                                                                                                    |                 |   |            |           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 0311021689/24/02/2023                                                                                                          |                 |         |              |           |         |                |      |         |              |      |   |                                                                                                                                |                 |   |            |           |   |                                                                                                                    |                 |   |            |           |
| <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/Sep/202223/8 dated 23/09/2022</b> against advance authorization No. <b>0311007049 dated 17/09/2021</b>, it was decided to fixadhoc 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>Festal Dragees (Tablets) Enterosoluble 10x10s((Total net Weight, Pancreatin 76800.00 Kgs Strength of Pancreatin 192mg/Tablet))</td> <td>1 Number Tablet</td> <td>1</td> <td>Pancreatin</td> <td>195.84 mg</td> </tr> <tr> <td>2</td> <td>Festal N Dragees (Tablets) 2x10s((Total net Weight, Pancreatin 5312.5 Kgs Strength of Pancreatin 212.50mg/Tablet))</td> <td>1 Number Tablet</td> <td>2</td> <td>Pancreatin</td> <td>216.75 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 | Festal Dragees (Tablets) Enterosoluble 10x10s((Total net Weight, Pancreatin 76800.00 Kgs Strength of Pancreatin 192mg/Tablet)) | 1 Number Tablet | 1 | Pancreatin | 195.84 mg | 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 |
| Sl. No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Export product                                                                                                                 | Qty.            | Sl. No. | Import items | Qty.      |         |                |      |         |              |      |   |                                                                                                                                |                 |   |            |           |   |                                                                                                                    |                 |   |            |           |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Festal Dragees (Tablets) Enterosoluble 10x10s((Total net Weight, Pancreatin 76800.00 Kgs Strength of Pancreatin 192mg/Tablet)) | 1 Number Tablet | 1       | Pancreatin   | 195.84 mg |         |                |      |         |              |      |   |                                                                                                                                |                 |   |            |           |   |                                                                                                                    |                 |   |            |           |
| 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 |         |                |      |         |              |      |   |                                                                                                                                |                 |   |            |           |   |                                                                                                                    |                 |   |            |           |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                | 64 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                             | Case Approved                              |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                              | BRAWN LABORATORIES LIMITED                 |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                 | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                          | HQRNORM APPLY 00006591AM23                 |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                          | 05AX04003295 AM23                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                     | 0511017494/24/02/2023                      |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. <b>NC/3/MEET/Dec/202223/15 dated 29/12/2022</b> against advance authorization No. <b>0511013337 dated 21/06/2022</b>, it was decided to fix ad-hoc 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. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 65 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | FDC LIMITED                                |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006576AM23                 |
| RA File Number          | 03AX04005701 AM23                          |
| Licence No and Date     | 0311021683/24/02/2023                      |

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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 5 ML ((EACH VIAL CONTAINS BRIMONIDINE L TARTRATE 0.01 GM NET WT OF BULK DRUG IS 1.070 KGS)) | 1 Vial | 1       | BRIMONIDINE L TARTRATE | 10.2 mg / vial |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 66 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | SOLARA ACTIVE PHARMA SCIENCES LIMITED      |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006579AM23                 |
| RA File Number          | 04AX04001001 AM23                          |

|                                                                                                                                                                                                                                                                                                                                                                                                                      |                       |         |                        |           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------|------------------------|-----------|
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                  | 0411004937/24/02/2023 |         |                        |           |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                            |                       |         |                        |           |
| <p>The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.<b>NC/3/MEET/Apr/202324/1 dated 28/04/2023</b> against advance authorization <b>No. 0411004581 dated 07/12/2022</b>, it was decided to fix ad-hoc 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.      |
| IBUPROFEN                                                                                                                                                                                                                                                                                                                                                                                                            | 1 kg.                 | 1       | Isobutyl Acetophenone  | 1.11 kg.  |
|                                                                                                                                                                                                                                                                                                                                                                                                                      |                       | 2       | Sodium Metal           | 0.235 kg. |
|                                                                                                                                                                                                                                                                                                                                                                                                                      |                       | 3       | Monochloro Acetic Acid | 0.919 kg. |
|                                                                                                                                                                                                                                                                                                                                                                                                                      |                       | 4       | Isopropyl Alcohol      | 0.50 kg.  |
|                                                                                                                                                                                                                                                                                                                                                                                                                      |                       | 5       | Sodium Dichromate      | 0.630 kg. |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                          |                       |         |                        |           |

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                           | 67 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                        | Case Approved                              |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                         | MACLEODS PHARMACEUTICALS LTD               |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                            | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                     | HQRNORM APPLY 00006580AM23                 |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                     | 03AX04005710 AM23                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                | 0311021583/24/02/2023                      |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                                                          |                                            |
| <p><b>Decision:</b> The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting <b>No.NC/3/MEET/Apr/202324/1</b> dated <b>28/04/2023</b> against advance authorization <b>No.0311020446</b> dated <b>03/01/2023</b>, it was decided to fix ad-hoc 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.                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|-------------------------------------------------------------------------------------------------|------------------------|
| Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 5400.000 kgs Dolutegravir Sodium + 32400.000 kgs Tenofovir Disoproxil Fumarate + 32400.000 kgs Lamivudine)) | 1 Number | 1       | (R)-3-AMINO-1-BUTANOL                                                                           | 19.635 mg.             |
|                                                                                                                                                                                                                                                                                                                |          | 2       | 1-(2,2-dimethoxyethyl)-5-methoxy-6(methoxycarbonyl) 4-oxo-1,4-dihydropyridine-3-carboxylic acid | Indigenously procured  |
|                                                                                                                                                                                                                                                                                                                |          | 3       | (R)-9-(2-phosphonomethoxy propyl)-adenine                                                       | 198.676 mg.            |
|                                                                                                                                                                                                                                                                                                                |          | 4       | LAMIVUDINE                                                                                      | Indigenously procured. |

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

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| Case No.                                                                                                                                                                                                                                                                                                                                                                                                  | 68 / NC/3/MEET/Jun/202324/6                |  |  |  |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                               | Case Approved                              |  |  |  |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                | YASHO INDUSTRIES LIMITED                   |  |  |  |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                   | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |  |  |  |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                            | HQRNORM APPLY 00006601AM23                 |  |  |  |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                            | 03AX04005798 AM23                          |  |  |  |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                       | 0311021713/26/02/2023                      |  |  |  |
| 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/Feb/202223/20</b> dated <b>24/02/2023</b> against advance authorization No. <b>0311014080 dt. 22/04/2022</b> , it was decided to fix 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.                | 69 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | YASHO INDUSTRIES LIMITED                   |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006602AM23                 |
| RA File Number          | 03AX04005806 AM23                          |
| Licence No and Date     | 0311021714/26/02/2023                      |

**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/202223/20 dated 24/02/2023** against advance authorization No. **0311014080 dt. 22/04/2022**, it was decided to fix 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.      |
|----------------------------------------------------------|-------|---------|--------------------|-----------|
| HYDROQUINONE BIS(2 Hydroxy Ethyl Ether) (YAPOX LM 30/10) | 1 kg. | 1       | HYDROQUINONE       | 0.579 kg. |
|                                                          |       | 2       | ETHYLENE CARBONATE | 0.934 kg. |

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

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| Case No.                | 70 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | INTAS PHARMACEUTICALS LIMITED              |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006642AM23                 |
| RA File Number          | 08AX04001990 AM23                          |
| Licence No and Date     | 0811007390/27/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. 4/82-ALC4/2019** dated **19/07/2019** against advance authorization **No.0810142125 dated 08/03/2018**, it was decided to fix ad-hoc 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.                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|----------------------------------------------|----------------------|
| SPIRONOLACTONE TABLETS BP 25 MG(EACH FILM COATED TABLET CONTAINS: SPIRONOLACTONE PH.EUR. 25 MG)                                                                    | 1 Number | 1       | SPIRONOLACTONE EP / BP / IP / USP / PH. EUR. | 25.50 mg per Tablet  |
| SPIRONOLACTONE TABLETS BP 50 MG(EACH FILM COATED TABLET CONTAINS: SPIRONOLACTONE PH.EUR. 50 MG)                                                                    | 1 Number | 2       | SPIRONOLACTONE EP / BP / IP / USP / PH. EUR. | 51.00 mg per Tablet  |
| SPIRONOLACTONE TABLETS BP 100 MG(EACH FILM COATED TABLET CONTAINS: SPIRONOLACTONE PH.EUR. 100 MG [IN WHICH ACTIVE INGREDIENT SPIRONOLACTONE USED IS 116.250 KGS.]) | 1 Number | 3       | SPIRONOLACTONE EP / BP / IP / USP / PH. EUR. | 102.00 mg per tablet |

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

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| Case No.                                                                                                                                                                                                                                                                                                                                                                              | 71 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                           | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                                                                                                                                                            | KOPRAN LIMITED                             |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                               | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                        | HQRNORM APPLY 00006649AM23                 |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                        | 03AX04005732 AM23                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                   | 0311021773/27/02/2023                      |
| <p>Norms Committee Decision:</p> <p><b>The committee considered the request of firm for fixation of ad-hoc norms and it was observed that review case of the firm for same export item against the Advance Authorisation No. 0311004745 dated 19/06/2021 is already under consideration. Hence, the committee decided to defer the case till the finalization of review case.</b></p> |                                            |

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|-------------------------|--------------------------------------------|
| Case No.                | 72 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Deferred                              |
| Party Name              | KOPRAN LIMITED                             |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |

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| HQ File Number                                                                                                                                                                                                                                                                                                                                | HQRNORM APPLY 00006648AM23 |
| RA File Number                                                                                                                                                                                                                                                                                                                                | 03AX04005729 AM23          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                           | 0311021772/27/02/2023      |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                     |                            |
| <b>The committee considered the request of firm for fixation of ad-hoc norms and it was observed that review case of the firm for same export item against the Advance Authorisation No. 0311004745 dated 19/06/2021 is already under consideration. Hence, the committee decided to defer the case till the finalization of review case.</b> |                            |

| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 73 / NC/3/MEET/Jun/202324/6                |                |                                                         |                   |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |
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| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Case Approved                              |                |                                                         |                   |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | INTAS PHARMACEUTICALS LIMITED              |                |                                                         |                   |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |                |                                                         |                   |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | HQRNORM APPLY 00006613AM23                 |                |                                                         |                   |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 08AX04002002 AM23                          |                |                                                         |                   |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 0811007388/27/02/2023                      |                |                                                         |                   |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                            |                |                                                         |                   |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |
| The Committee considered the case as per agenda and it was decided to fix ad-hoc 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>PROPAFENONE HYDROCHLORIDE TABLETS 150 MG(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 150 MG)</td><td>1 Tablet</td><td>1</td><td>PROPAFENONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR.</td><td>153.00 mg/tablet</td></tr><tr><td>PROPAFENONE HYDROCHLORIDE TABLETS 300 MG(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 300 MG [IN WHICH ACTIVE INGREDIENT PROPAFENONE HYDROCHLORIDE USED IS 283.500 KGS.])</td><td>1 Tablet</td><td>2</td><td>PROPAFENONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR.</td><td>306.00 mg/ tablet</td></tr></table> |                                            | Export Product | Qty.                                                    | Sl. No.           | Import Items | Qty. | PROPAFENONE HYDROCHLORIDE TABLETS 150 MG(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 150 MG) | 1 Tablet | 1 | PROPAFENONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. | 153.00 mg/tablet | PROPAFENONE HYDROCHLORIDE TABLETS 300 MG(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 300 MG [IN WHICH ACTIVE INGREDIENT PROPAFENONE HYDROCHLORIDE USED IS 283.500 KGS.]) | 1 Tablet | 2 | PROPAFENONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. | 306.00 mg/ tablet |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Qty.                                       | Sl. No.        | Import Items                                            | Qty.              |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |
| PROPAFENONE HYDROCHLORIDE TABLETS 150 MG(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 150 MG)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 1 Tablet                                   | 1              | PROPAFENONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. | 153.00 mg/tablet  |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |
| PROPAFENONE HYDROCHLORIDE TABLETS 300 MG(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 300 MG [IN WHICH ACTIVE INGREDIENT PROPAFENONE HYDROCHLORIDE USED IS 283.500 KGS.])                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 1 Tablet                                   | 2              | PROPAFENONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. | 306.00 mg/ tablet |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |
| RA concerned may take necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                            |                |                                                         |                   |              |      |                                                                                                                       |          |   |                                                         |                  |                                                                                                                                                                                                   |          |   |                                                         |                   |

|             |                             |
|-------------|-----------------------------|
| Case No.    | 74 / NC/3/MEET/Jun/202324/6 |
| Case Status | Case Deferred               |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | INDO AMINES LIMITED                        |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | HQRNORM APPLY 00006610AM23                 |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 03AX04005572 AM23                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 0311021737/27/02/2023                      |
| <p>Norms Committee Decision:</p> <p>The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-</p> <p><b>I. Reason for asking very high quantity of styrene comparing to theoretical yield.</b></p> <p><b>II. Yield of the reaction with justification.</b></p> <p><b>III. Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.</b></p> |                                            |

|                                                                                                                                                                                                                                                                                                                                                                                                            |                                            |                |                                                                                                                                                        |         |              |      |                                         |      |   |                                                                                                                                                        |         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|---------|--------------|------|-----------------------------------------|------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                   | 75 / NC/3/MEET/Jun/202324/6                |                |                                                                                                                                                        |         |              |      |                                         |      |   |                                                                                                                                                        |         |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                | Case Approved                              |                |                                                                                                                                                        |         |              |      |                                         |      |   |                                                                                                                                                        |         |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                 | AMOLI ORGANICS PRIVATE LIMITED             |                |                                                                                                                                                        |         |              |      |                                         |      |   |                                                                                                                                                        |         |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                    | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |                |                                                                                                                                                        |         |              |      |                                         |      |   |                                                                                                                                                        |         |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                             | HQRNORM APPLY 00006607AM23                 |                |                                                                                                                                                        |         |              |      |                                         |      |   |                                                                                                                                                        |         |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                             | 03AX04005558 AM23                          |                |                                                                                                                                                        |         |              |      |                                         |      |   |                                                                                                                                                        |         |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                        | 0311021734/27/02/2023                      |                |                                                                                                                                                        |         |              |      |                                         |      |   |                                                                                                                                                        |         |
| 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/Dec/202223/15dated 29/12/2022</b> against advance authorization No. <b>0311015623 dated 17/06/2022</b> , it was decided to fix 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>Rosuvastatin Calcium USP / BP / EP / IH</td><td>1 kg</td><td>1</td><td>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</td><td>1.30 kg</td></tr></table>                              |                                            | 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 |
| 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. | 76 / NC/3/MEET/Jun/202324/6 |
|----------|-----------------------------|

| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Case Approved                              |                |                |         |              |      |                   |      |   |                |         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------|----------------|---------|--------------|------|-------------------|------|---|----------------|---------|
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | ALTA LABORATORIES LIMITED                  |                |                |         |              |      |                   |      |   |                |         |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |                |                |         |              |      |                   |      |   |                |         |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | HQRNORM APPLY 00006606AM23                 |                |                |         |              |      |                   |      |   |                |         |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 03AX04005719 AM23                          |                |                |         |              |      |                   |      |   |                |         |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 0311021732/27/02/2023                      |                |                |         |              |      |                   |      |   |                |         |
| <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/202223/15 dated 29/12/2022</b> against advance authorization No. <b>0311015468 dated 13/06/2022</b>, it was decided to fix 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>SODIUM SALICYLATE</td><td>1 kg</td><td>1</td><td>SALICYLIC ACID</td><td>0.80 kg</td></tr> </table> <p>RA concerned may take further necessary action as per above decision of NC.</p> |                                            | 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 |              |      |                   |      |   |                |         |

| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 77 / NC/3/MEET/Jun/202324/6                |                |              |         |              |      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------|--------------|---------|--------------|------|
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Case Approved                              |                |              |         |              |      |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | SOLARA ACTIVE PHARMA SCIENCES LIMITED      |                |              |         |              |      |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |                |              |         |              |      |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | HQRNORM APPLY 00006655AM23                 |                |              |         |              |      |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 04AX04001034 AM23                          |                |              |         |              |      |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 0411004963/28/02/2023                      |                |              |         |              |      |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.<b>NC/3/MEET/Apr/202324/1 dated 28/04/2023</b> against advance authorization <b>No. 0411004581 dated 07/12/2022</b>, it was decided to fix ad-hoc 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> </table> |                                            | Export Product | Qty.         | Sl. No. | Import Items | Qty. |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Qty.                                       | Sl. No.        | Import Items | Qty.    |              |      |

|           |       |   |                        |           |
|-----------|-------|---|------------------------|-----------|
| IBUPROFEN | 1 kg. | 1 | Isobutyl Acetophenone  | 1.11 kg.  |
|           |       | 2 | Sodium Metal           | 0.235 kg. |
|           |       | 3 | Monochloro Acetic Acid | 0.919 kg. |
|           |       | 4 | Isopropyl Alcohol      | 0.50 kg.  |
|           |       | 5 | Sodium Dichromate      | 0.630 kg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 78 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | AUROBINDO PHARMA LTD                       |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006657AM23                 |
| RA File Number          | 09AX04001022 AM23                          |
| Licence No and Date     | 0911004550/28/02/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **no. NC/3/MEET/Mar/20202223/24 dated 13/04/2023** against advance authorization **no. 0911001956 dated 29/11/2021**, it was decided to fix 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.      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------|-------------------------------------------------------------------------------------------------|-----------|
| <b>AMOXYCILLIN AND CLAVULANATE POTASSIUM TABLETS 1000mg((Each tablet contains Amoxicillin 875 mg and Potassium Clavulanate equivalent to Clavulanic acid 125 mg) [Relevant Bulk Drug content in the Export product is Amoxycillin Trihydrate is 11812.50 Kgs and Clavulanate potassium is 1687.50 Kgs])</b> | 1 Number Tablet | 1       | 6-Amino Penicillanic Acid (6-APA)                                                               | 576.40 mg |
|                                                                                                                                                                                                                                                                                                             |                 | 2       | D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]                                          | 496.38 mg |
|                                                                                                                                                                                                                                                                                                             |                 | 3       | Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads) | 2.25 mg   |
|                                                                                                                                                                                                                                                                                                             |                 |         |                                                                                                 |           |

|                                                                             |  |   |                                                                     |           |
|-----------------------------------------------------------------------------|--|---|---------------------------------------------------------------------|-----------|
|                                                                             |  | 4 | Potassium Clavulanate Diluted with Microcrystalline Cellulose (1:1) | 302.03 mg |
| RA concerned may take further necessary action as per above decision of NC. |  |   |                                                                     |           |

| Case No.                                                                                                                                                                                                                                                                                                                        | 79 / NC/3/MEET/Jun/202324/6                |         |                     |            |                |      |         |              |      |                                                                                                                   |              |   |                     |            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------|---------------------|------------|----------------|------|---------|--------------|------|-------------------------------------------------------------------------------------------------------------------|--------------|---|---------------------|------------|
| Case Status                                                                                                                                                                                                                                                                                                                     | Case Approved                              |         |                     |            |                |      |         |              |      |                                                                                                                   |              |   |                     |            |
| Party Name                                                                                                                                                                                                                                                                                                                      | FDC LIMITED                                |         |                     |            |                |      |         |              |      |                                                                                                                   |              |   |                     |            |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                         | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |         |                     |            |                |      |         |              |      |                                                                                                                   |              |   |                     |            |
| HQ File Number                                                                                                                                                                                                                                                                                                                  | HQRNORM APPLY 00006668AM23                 |         |                     |            |                |      |         |              |      |                                                                                                                   |              |   |                     |            |
| RA File Number                                                                                                                                                                                                                                                                                                                  | 03AX04005749 AM23                          |         |                     |            |                |      |         |              |      |                                                                                                                   |              |   |                     |            |
| Licence No and Date                                                                                                                                                                                                                                                                                                             | 0311021795/28/02/2023                      |         |                     |            |                |      |         |              |      |                                                                                                                   |              |   |                     |            |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                       |                                            |         |                     |            |                |      |         |              |      |                                                                                                                   |              |   |                     |            |
| The Committee considered the case as per agenda and it was decided to fix ad-hoc 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>GENTAMICIN EYE/EAR DROPS 10 ML((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.030GM NET WT OF BULK DRUG IS 4.110 KGS))</td><td>137000 Vials</td><td>1</td><td>GENTAMICIN SULPHATE</td><td>4.1922 kg.</td></tr></table> |                                            |         |                     |            | Export Product | Qty. | Sl. No. | Import Items | Qty. | GENTAMICIN EYE/EAR DROPS 10 ML((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.030GM NET WT OF BULK DRUG IS 4.110 KGS)) | 137000 Vials | 1 | GENTAMICIN SULPHATE | 4.1922 kg. |
| Export Product                                                                                                                                                                                                                                                                                                                  | Qty.                                       | Sl. No. | Import Items        | Qty.       |                |      |         |              |      |                                                                                                                   |              |   |                     |            |
| GENTAMICIN EYE/EAR DROPS 10 ML((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.030GM NET WT OF BULK DRUG IS 4.110 KGS))                                                                                                                                                                                                               | 137000 Vials                               | 1       | GENTAMICIN SULPHATE | 4.1922 kg. |                |      |         |              |      |                                                                                                                   |              |   |                     |            |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                     |                                            |         |                     |            |                |      |         |              |      |                                                                                                                   |              |   |                     |            |

|                           |                                            |
|---------------------------|--------------------------------------------|
| Case No.                  | 80 / NC/3/MEET/Jun/202324/6                |
| Case Status               | Case Approved                              |
| Party Name                | VINYL PRODUCTS PRIVATE LIMITED             |
| Meeting Number and Date   | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number            | HQRNORM APPLY 00006693AM23                 |
| RA File Number            | 05AX04003380 AM23                          |
| Licence No and Date       | 0511017572/01/03/2023                      |
| Norms Committee Decision: |                                            |

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.     |
|-------------------------------------------|-------|---------|--------------------|----------|
| PVC Plasticizer (Phthalic, Non-Polymeric) | 1 kg. | 1       | Phthalic Anhydride | 0.40 kg. |
|                                           |       | 2       | 2 Ethyl Hexanol    | 0.70 kg. |

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

|                                                       |                                            |
|-------------------------------------------------------|--------------------------------------------|
| Case No.                                              | 81 / NC/3/MEET/Jun/202324/6                |
| Case Status                                           | Case Deferred                              |
| Party Name                                            | ENCUBE ETHICALS PRIVATE LIMITED            |
| Meeting Number and Date                               | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                        | HQRNORM APPLY 00006678AM23                 |
| RA File Number                                        | 03AX04005502 AM23                          |
| Licence No and Date                                   | 0311021802/01/03/2023                      |
| Norms Committee Decision:                             |                                            |
| <b>Under consideration for physical verification.</b> |                                            |

|                                                                                                                                                                                                                                                |                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                       | 82 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                    | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                     | AARTI PHARMALABS LIMITED                   |
| Meeting Number and Date                                                                                                                                                                                                                        | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                 | HQRNORM APPLY 00006751AM23                 |
| RA File Number                                                                                                                                                                                                                                 | 03AX04005685 AM23                          |
| Licence No and Date                                                                                                                                                                                                                            | 0311021895/04/03/2023                      |
| Norms Committee Decision:                                                                                                                                                                                                                      |                                            |
| The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-                                                                                |                                            |
| <ol style="list-style-type: none"> <li><b>Yield of reaction with justification of wastage at each stage.</b></li> <li><b>Function of sodium sulphate &amp; urea in the reaction and also to give reason for indicating Ammonium</b></li> </ol> |                                            |

**Sulphate in the process flow chart.**

3. **Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.**

|                                                                                                                                                                                                                                               |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                      | 83 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                   | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                    | BLUE JET HEALTHCARE LIMITED                |
| Meeting Number and Date                                                                                                                                                                                                                       | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                | HQRNORM APPLY 00006770AM23                 |
| RA File Number                                                                                                                                                                                                                                | 03AX04005861 AM23                          |
| Licence No and Date                                                                                                                                                                                                                           | 0311021934/06/03/2023                      |
| Norms Committee Decision:                                                                                                                                                                                                                     |                                            |
| <b>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.</b> |                                            |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 84 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                       | MEDREICH LIMITED                           |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                          | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                   | HQRNORM APPLY 00006767AM23                 |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 07AX04001781 AM23                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                              | 0711006639/06/03/2023                      |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                            |
| The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-                                                                                                                                                                                                                                                                                                  |                                            |
| <ol style="list-style-type: none"> <li>1. <b>Copy of Drug Manufacturing License (DML).</b></li> <li>2. <b>Copy of Master Batch Formula</b></li> <li>3. <b>Copy of Advance Authorisation</b></li> <li>4. <b>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.</b></li> </ol> |                                            |

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 85 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Deferred                              |
| Party Name              | ANUH PHARMA LIMITED                        |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | HQRNORM APPLY 00006763AM23 |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 03AX04005850 AM23          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 0311021914/06/03/2023      |
| <p>Norms Committee Decision:</p> <p>The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-</p> <ol style="list-style-type: none"> <li>1. <b>Stepwise complete chemistry, with molecular weight and percentage yield on molar basis.</b></li> <li>2. <b>Copy of technical literature in support of yield envisaged in the process.</b></li> <li>3. <b>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.</b></li> </ol> |                            |

|                                                                                               |                                            |
|-----------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                      | 86 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                   | Case Deferred                              |
| Party Name                                                                                    | ENCUBE ETHICALS PRIVATE LIMITED            |
| Meeting Number and Date                                                                       | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                | HQRNORM APPLY 00006779AM23                 |
| RA File Number                                                                                | 03AX04005915 AM23                          |
| Licence No and Date                                                                           | 0311021940/07/03/2023                      |
| <p>Norms Committee Decision:</p> <p><b>Under consideration for physical verification.</b></p> |                                            |

|                                                                                                                                                                                                                                                            |                                            |                |                          |           |              |      |                                           |             |   |                          |           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------|--------------------------|-----------|--------------|------|-------------------------------------------|-------------|---|--------------------------|-----------|
| Case No.                                                                                                                                                                                                                                                   | 87 / NC/3/MEET/Jun/202324/6                |                |                          |           |              |      |                                           |             |   |                          |           |
| Case Status                                                                                                                                                                                                                                                | Case Approved                              |                |                          |           |              |      |                                           |             |   |                          |           |
| Party Name                                                                                                                                                                                                                                                 | LYRUS LIFE SCIENCES PRIVATE LIMITED        |                |                          |           |              |      |                                           |             |   |                          |           |
| Meeting Number and Date                                                                                                                                                                                                                                    | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |                |                          |           |              |      |                                           |             |   |                          |           |
| HQ File Number                                                                                                                                                                                                                                             | HQRNORM APPLY 00006780AM23                 |                |                          |           |              |      |                                           |             |   |                          |           |
| RA File Number                                                                                                                                                                                                                                             | 07AX04001780 AM23                          |                |                          |           |              |      |                                           |             |   |                          |           |
| Licence No and Date                                                                                                                                                                                                                                        | 0711006647/07/03/2023                      |                |                          |           |              |      |                                           |             |   |                          |           |
| Norms Committee Decision:                                                                                                                                                                                                                                  |                                            |                |                          |           |              |      |                                           |             |   |                          |           |
| The Committee considered the case as per agenda and it was decided to fix ad-hoc 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>NITROFURANTOIN ORAL SUSPENSION 1.5G/300ML</td><td>9333 Number</td><td>1</td><td>NITROFURANTOIN DIHYDRATE</td><td>14.28 kg.</td></tr></table> |                                            | Export Product | Qty.                     | Sl. No.   | Import Items | Qty. | NITROFURANTOIN ORAL SUSPENSION 1.5G/300ML | 9333 Number | 1 | NITROFURANTOIN DIHYDRATE | 14.28 kg. |
| Export Product                                                                                                                                                                                                                                             | Qty.                                       | Sl. No.        | Import Items             | Qty.      |              |      |                                           |             |   |                          |           |
| NITROFURANTOIN ORAL SUSPENSION 1.5G/300ML                                                                                                                                                                                                                  | 9333 Number                                | 1              | NITROFURANTOIN DIHYDRATE | 14.28 kg. |              |      |                                           |             |   |                          |           |

|                                            |             |   |                             |          |
|--------------------------------------------|-------------|---|-----------------------------|----------|
| NITROFURANTOIN ORAL<br>SUSPENSION 3G/300ML | 2000 Number | 2 | NITROFURANTOIN<br>DIHYDRATE | 6.12 kg. |
|--------------------------------------------|-------------|---|-----------------------------|----------|

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

|                            |                                            |
|----------------------------|--------------------------------------------|
| Case No.                   | 88 / NC/3/MEET/Jun/202324/6                |
| Case Status                | Case Approved                              |
| Party Name                 | LYRUS LIFE SCIENCES PRIVATE LIMITED        |
| Meeting Number<br>and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number             | HQRNORM APPLY 00006781AM23                 |
| RA File Number             | 07AX04001758 AM23                          |
| Licence No and<br>Date     | 0711006648/07/03/2023                      |

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to fix ad-hoc 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.                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------|----------|---------|------------------|-----------------------|
| ALVERINE CITRATE 60MG CAPSULES<br>STOMACH PAIN & CRAMPS<br>RELIEF(ALVERIN CITRATE 60MG<br>CAPSULES NLS P - STOMACH PAIN &<br>CRAMPS RELIEF 100's)  | 1 Number | 1       | ALVERINE CITRATE | 60 mg<br>per capsule  |
| ALVERINE CITRATE 120MG CAPSULES<br>STOMACH PAIN & CRAMPS<br>RELIEF(ALVERIN CITRATE 120MG<br>CAPSULES NLS P - STOMACH PAIN &<br>CRAMPS RELIEF 60's) | 1 Number | 2       | ALVERINE CITRATE | 120 mg<br>per capsule |

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

|             |                             |
|-------------|-----------------------------|
| Case No.    | 89 / NC/3/MEET/Jun/202324/6 |
| Case Status | Case Deferred               |
| Party Name  | ZYDUS LIFESCIENCES LIMITED  |

|                                                                                                                                                                                                                                                                                       |                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Meeting Number and Date                                                                                                                                                                                                                                                               | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                        | HQRNORM APPLY 00006783AM23                 |
| RA File Number                                                                                                                                                                                                                                                                        | 08AX04001767 AM23                          |
| Licence No and Date                                                                                                                                                                                                                                                                   | 0811007464/07/03/2023                      |
| <p>Norms Committee Decision:</p> <p><b>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.</b></p> |                                            |

|                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     |      |         |                     |          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------|---------|---------------------|----------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                 | 90 / NC/3/MEET/Jun/202324/6                                                         |      |         |                     |          |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                              | Case Approved                                                                       |      |         |                     |          |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                               | GLOBAL CALCIUM PRIVATE LIMITED                                                      |      |         |                     |          |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                  | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023                                          |      |         |                     |          |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                           | HQRNORM APPLY 00006785AM23                                                          |      |         |                     |          |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                           | 04AX04001029 AM23                                                                   |      |         |                     |          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                      | 0711006656/07/03/2023                                                               |      |         |                     |          |
| 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/Dec/202223/17 dated 13/01/2023</b> against advance authorization No. <b>0711002615dated 13/12/2021</b> , it was decided to fix 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/ NONAHYDRATE Eur.Ph/ ANHYDROUS Eur.Ph/ DODECAHYDRATE Eur.Ph) | 1 kg | 1       | CITRIC ACID         | 1.001 kg |
|                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     |      | 2       | MAGNESIUM CARBONATE | 0.730 kg |
| 2                                                                                                                                                                                                                                                                                                                                                                                                        | CALCIUM CITRATE(USP)                                                                | 1 kg | 1       | CITRIC ACID         | 0.816 kg |
|                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     |      | 2       | CALCIUM CARBONATE   | 0.660 kg |
| 3                                                                                                                                                                                                                                                                                                                                                                                                        | ZINC CITRATE (USP)                                                                  | 1 kg | 1       | CITRIC ACID         | 0.880 kg |
| 4                                                                                                                                                                                                                                                                                                                                                                                                        | POTASSIUM CITRATE (BP/Eur.Ph/ USP)                                                  | 1 kg | 1       | CITRIC ACID         | 0.859 kg |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 91 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | ARORA AROMATICS PRIVATE LIMITED            |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006787AM23                 |
| RA File Number          | 05AX04003415 AM23                          |
| Licence No and Date     | 0511017652/07/03/2023                      |

**Norms Committee Decision:**

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/May/202324/4** dated **26/05/2023** against advance authorization **No.0310835906** dated **25/04/2020**, it was decided to fix ad-hoc 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.     |
|------------------|-------|---------|------------------|----------|
| Menthol Crystals | 1 kg. | 1       | L Menthol Molten | 1.02 kg. |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 92 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Deferred                              |
| Party Name              | SCOTT EDIL PHARMACIA LIMITED               |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006790AM23                 |
| RA File Number          | 30AX04000539 AM23                          |
| Licence No and Date     | 3011003243/07/03/2023                      |

**Norms Committee Decision:**

The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-

1. CoA from Foreign Supplier showing potency of import item.
2. Submit one shipping bill complete set of the export product along with export and import product

**statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.**

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 93 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Approved                              |
| Party Name              | SENTISS PHARMA PRIVATE LIMITED             |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006795AM23                 |
| RA File Number          | 05AX04003421 AM23                          |
| Licence No and Date     | 0511017659/07/03/2023                      |

**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/202223/8 dated 23/09/2022** against advance authorization No. **0511005004 dated 28/09/2021**, it was decided to fixadhoc 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.      |
|-------------------------------------------------------|---------------|---------|---------------------|-----------|
| TOBRISS (TOBRAMYCIN 0.31 PERCENT) EYE DROPS 5 ML VIAL | 1 Number Vial | 1       | Tobramycin Sulphate | 19.057 mg |

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

|                         |                                            |
|-------------------------|--------------------------------------------|
| Case No.                | 94 / NC/3/MEET/Jun/202324/6                |
| Case Status             | Case Deferred                              |
| Party Name              | AUORE LIFE SCIENCES PRIVATE LIMITED        |
| Meeting Number and Date | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number          | HQRNORM APPLY 00006807AM23                 |
| RA File Number          | 09AX04001097 AM23                          |
| Licence No and Date     | 0911004646/08/03/2023                      |

**Norms Committee Decision:**

**Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case..**

|                                                                                                                                                                                                                                                                                        |                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                               | 95 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                                                            | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                                                             | AUROBINDO PHARMA LTD                       |
| Meeting Number and Date                                                                                                                                                                                                                                                                | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                         | HQRNORM APPLY 00006808AM23                 |
| RA File Number                                                                                                                                                                                                                                                                         | 09AX04001078 AM23                          |
| Licence No and Date                                                                                                                                                                                                                                                                    | 0911004655/08/03/2023                      |
| <p>Norms Committee Decision:</p> <p><b>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case..</b></p> |                                            |

|                                                                                                                                                                                                                                                                                                                                                                                                  |                                            |                |                    |           |              |      |                                                          |       |   |              |           |   |                    |           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------|--------------------|-----------|--------------|------|----------------------------------------------------------|-------|---|--------------|-----------|---|--------------------|-----------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                         | 96 / NC/3/MEET/Jun/202324/6                |                |                    |           |              |      |                                                          |       |   |              |           |   |                    |           |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                      | Case Approved                              |                |                    |           |              |      |                                                          |       |   |              |           |   |                    |           |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                       | YASHO INDUSTRIES LIMITED                   |                |                    |           |              |      |                                                          |       |   |              |           |   |                    |           |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                          | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |                |                    |           |              |      |                                                          |       |   |              |           |   |                    |           |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                   | HQRNORM APPLY 00006886AM23                 |                |                    |           |              |      |                                                          |       |   |              |           |   |                    |           |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                   | 03AX04005958 AM23                          |                |                    |           |              |      |                                                          |       |   |              |           |   |                    |           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                              | 0311022020/09/03/2023                      |                |                    |           |              |      |                                                          |       |   |              |           |   |                    |           |
| 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/Feb/202223/20dated24/02/2023</b> against advance authorization No. <b>0311014080 dt. 22/04/2022</b> , it was decided to fix 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">HYDROQUINONE BIS(2 Hydroxy Ethyl Ether) (YAPOX LM 30/10)</td><td rowspan="2">1 kg.</td><td>1</td><td>HYDROQUINONE</td><td>0.579 kg.</td></tr><tr><td>2</td><td>ETHYLENE CARBONATE</td><td>0.934 kg.</td></tr></table>                                                  |                                            | Export product | Qty.               | Sl. No.   | Import items | Qty. | HYDROQUINONE BIS(2 Hydroxy Ethyl Ether) (YAPOX LM 30/10) | 1 kg. | 1 | HYDROQUINONE | 0.579 kg. | 2 | ETHYLENE CARBONATE | 0.934 kg. |
| Export product                                                                                                                                                                                                                                                                                                                                                                                   | Qty.                                       | Sl. No.        | Import items       | Qty.      |              |      |                                                          |       |   |              |           |   |                    |           |
| HYDROQUINONE BIS(2 Hydroxy Ethyl Ether) (YAPOX LM 30/10)                                                                                                                                                                                                                                                                                                                                         | 1 kg.                                      | 1              | HYDROQUINONE       | 0.579 kg. |              |      |                                                          |       |   |              |           |   |                    |           |
|                                                                                                                                                                                                                                                                                                                                                                                                  |                                            | 2              | ETHYLENE CARBONATE | 0.934 kg. |              |      |                                                          |       |   |              |           |   |                    |           |
| RA concerned may take further necessary action as per above decision of NC.                                                                                                                                                                                                                                                                                                                      |                                            |                |                    |           |              |      |                                                          |       |   |              |           |   |                    |           |

|             |                             |
|-------------|-----------------------------|
| Case No.    | 97 / NC/3/MEET/Jun/202324/6 |
| Case Status | Case Approved               |
| Party Name  | YASHO INDUSTRIES LIMITED    |

| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                          | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |         |                    |           |                |      |         |              |      |                                                          |       |   |              |           |   |                    |           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------|--------------------|-----------|----------------|------|---------|--------------|------|----------------------------------------------------------|-------|---|--------------|-----------|---|--------------------|-----------|
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                   | HQRNORM APPLY 00006885AM23                 |         |                    |           |                |      |         |              |      |                                                          |       |   |              |           |   |                    |           |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                   | 03AX04005936 AM23                          |         |                    |           |                |      |         |              |      |                                                          |       |   |              |           |   |                    |           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                              | 0311022019/09/03/2023                      |         |                    |           |                |      |         |              |      |                                                          |       |   |              |           |   |                    |           |
| <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/Feb/202223/20</b> dated <b>24/02/2023</b> against advance authorization No. <b>0311014080 dt. 22/04/2022</b>, it was decided to fix 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">HYDROQUINONE BIS(2 Hydroxy Ethyl Ether) (YAPOX LM 30/10)</td> <td rowspan="2">1 kg.</td> <td>1</td> <td>HYDROQUINONE</td> <td>0.579 kg.</td> </tr> <tr> <td>2</td> <td>ETHYLENE CARBONATE</td> <td>0.934 kg.</td> </tr> </tbody> </table>                                 |                                            |         |                    |           | Export product | Qty. | Sl. No. | Import items | Qty. | HYDROQUINONE BIS(2 Hydroxy Ethyl Ether) (YAPOX LM 30/10) | 1 kg. | 1 | HYDROQUINONE | 0.579 kg. | 2 | ETHYLENE CARBONATE | 0.934 kg. |
| Export product                                                                                                                                                                                                                                                                                                                                                                                                                                   | Qty.                                       | Sl. No. | Import items       | Qty.      |                |      |         |              |      |                                                          |       |   |              |           |   |                    |           |
| HYDROQUINONE BIS(2 Hydroxy Ethyl Ether) (YAPOX LM 30/10)                                                                                                                                                                                                                                                                                                                                                                                         | 1 kg.                                      | 1       | HYDROQUINONE       | 0.579 kg. |                |      |         |              |      |                                                          |       |   |              |           |   |                    |           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                            | 2       | ETHYLENE CARBONATE | 0.934 kg. |                |      |         |              |      |                                                          |       |   |              |           |   |                    |           |
| <p>RA concerned may take further necessary action as per above decision of NC.</p>                                                                                                                                                                                                                                                                                                                                                               |                                            |         |                    |           |                |      |         |              |      |                                                          |       |   |              |           |   |                    |           |

| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 98 / NC/3/MEET/Jun/202324/6                |         |              |           |                |      |         |              |      |                                           |      |   |             |           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|---------|--------------|-----------|----------------|------|---------|--------------|------|-------------------------------------------|------|---|-------------|-----------|
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Case Approved                              |         |              |           |                |      |         |              |      |                                           |      |   |             |           |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                            | KLJ PLASTICIZERS LIMITED.                  |         |              |           |                |      |         |              |      |                                           |      |   |             |           |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                               | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |         |              |           |                |      |         |              |      |                                           |      |   |             |           |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                        | HQRNORM APPLY 00006838AM23                 |         |              |           |                |      |         |              |      |                                           |      |   |             |           |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 05AX04003332 AM23                          |         |              |           |                |      |         |              |      |                                           |      |   |             |           |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 0511017678/09/03/2023                      |         |              |           |                |      |         |              |      |                                           |      |   |             |           |
| <p>Norms Committee Decision:</p> <p>The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting <b>No.NC/3/MEET/Jan/20202122/13</b> dated <b>21/01/2022</b> against advance authorization <b>No.0511004139</b> dated <b>16/08/2021</b>, it was decided to fix ad-hoc 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>TRI ETHYL CITRATE (TEC)(TRI ETHYL CITRATE</td> <td>1 kg</td> <td>1</td> <td>CITRIC ACID</td> <td>0.726 kg.</td> </tr> </tbody> </table>                                                                                                                                                                    |                                            |         |              |           | Export Product | Qty. | Sl. No. | Import Items | Qty. | TRI ETHYL CITRATE (TEC)(TRI ETHYL CITRATE | 1 kg | 1 | CITRIC ACID | 0.726 kg. |
| Export Product                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Qty.                                       | Sl. No. | Import Items | Qty.      |                |      |         |              |      |                                           |      |   |             |           |
| TRI ETHYL CITRATE (TEC)(TRI ETHYL CITRATE                                                                                                                                                                                                                                                                                                                                                                                                                             | 1 kg                                       | 1       | CITRIC ACID  | 0.726 kg. |                |      |         |              |      |                                           |      |   |             |           |

|                                                                                                                                                                       |  |   |                         |                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|---|-------------------------|-------------------------------|
| (TEC) (PACKED IN 400 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES (3,400.000 KGS. WITHOUT WASTAGE)) (EACH DRUM SHALL WEIGHT 8.5 KG AND STORAGE CAPACITY 250.000 KGS.)) |  | 2 | DENATURED ETHYL ALCOHOL | 0.526 kg.                     |
|                                                                                                                                                                       |  | 3 | HDPE GRANULES           | Relevant as per paking policy |

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

|                                                                                                                                                                                                                                                |                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                       | 99 / NC/3/MEET/Jun/202324/6                |
| Case Status                                                                                                                                                                                                                                    | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                     | ZYDUS LIFESCIENCES LIMITED                 |
| Meeting Number and Date                                                                                                                                                                                                                        | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                 | HQRNORM APPLY 00006898AM23                 |
| RA File Number                                                                                                                                                                                                                                 | 08AX04002105 AM23                          |
| Licence No and Date                                                                                                                                                                                                                            | 0811007519/10/03/2023                      |
| Norms Committee Decision:                                                                                                                                                                                                                      |                                            |
| <b>Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case..</b> |                                            |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Case No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 100 / NC/3/MEET/Jun/202324/6               |
| Case Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Case Deferred                              |
| Party Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | BLUE JET HEALTHCARE LIMITED                |
| Meeting Number and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NC/ 3/ MEET/ Jun/ 202324/ 6 and 14/06/2023 |
| HQ File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | HQRNORM APPLY 00000740AM24                 |
| RA File Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 03AX04000488 AM24                          |
| Licence No and Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 0311023468/10/05/2023                      |
| Norms Committee Decision:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                            |
| The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-                                                                                                                                                                                                                                                                                                                                                                |                                            |
| <ol style="list-style-type: none"> <li>1. To give molecular weight of reactants &amp; product of the chemical reaction with calculation sheet and percentage yield.</li> <li>2. Justification for low yield of the reaction.</li> <li>3. End use of the product.</li> <li>4. Submit one shipping bill complete set of the export product along with export and import product statement of the said Authorization. Also, it is directed to technical expert to give their comments before next agenda of this case.</li> </ol> |                                            |

