



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / व्यापार महकमा

Directorate General of Foreign Trade / विदेश व्यापार महानिदेशालय

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

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

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(DES - III SECTION)**MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Oct/202223/11**DATED:** 31/10/2022**Please Note**

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

Meeting No. NC/3/MEET/Oct/202223/11 dated 31/10/2022 of Norms Committee - III for the year 2022-23 was held on 31/10/2022 under the Chairmanship of Rajiv Soni ,Joint DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2015-20.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	AJAY KUMAR, Deputy Director	Directorate General of Foreign Trade, Delhi
2	NAND Lal, Technical Authority	Technical Consultant, DGFT
3	SHAISH KUMAR, Technical Authority	Technical Consultant, DGFT
4	DINESHNARAIN MATHUR, Technical Authority	Technical Consultant, DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Oct/202223/11
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Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00001942AM23
RA File Number	NA
Licence No and Date	0910067796/null
Norms Committee Decision: The Committee considered the request of the firm for enhancement of norms and it was observed that the firm had earlier represented its case for enhancement of norms and was called to attend Personal Hearing. The firm had attended the Personal Hearing in Meeting No. NC/3/MEET/Apr/202223/2 dated 20.04.2022 and after hearing the explanation of the Representatives of firm, it was observed that the export description given in this Advance Authorization is not from non- infringing process. Moreover, it was also noted by the committee that the firm is a regular exporter of these pharma items but have not taken any licence under non- infringing clause directly from RA , as per the policy provision given under para 4.18 of HBP Vol. I. The Representative of firm also agreed with observation of the committee that the exports are being made under buy back arrangement. Accordingly, the request of firm was rejected. Now, the firm has again requested for enhancement in the quantity of import items. In view of above, the Committee decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	2 / NC/3/MEET/Oct/202223/11
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00000951AM23
RA File Number	092404000017 AM14
Licence No and Date	0910055800/19/04/2013
Norms Committee Decision: The Committee considered the request of the firm for enhancement of norms and it was observed that the firm had earlier represented its case for enhancement of norms and was called to attend Personal Hearing. The firm had attended the Personal Hearing in Meeting No. NC/3/MEET/Apr/202223/2 dated 20.04.2022 and after hearing the explanation of the Representatives of firm, it was observed that the export description given in this Advance Authorization is not from non- infringing process. Moreover, it was also noted by the committee that the firm is a regular exporter of these pharma items but have not taken any licence under non- infringing clause directly from RA , as per the policy provision given under para 4.18 of HBP Vol. I. The Representative of firm also agreed with observation of the committee that the exports are being made under buy back arrangement. Accordingly, the request of firm was rejected.	

Now, the firm has again requested for enhancement in the quantity of import items. In view of above, the Committee decided to **reject** the case maintaining the status quo.

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

Case No.	3 / NC/3/MEET/Oct/202223/11
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00000972AM23
RA File Number	092404000139 AM15
Licence No and Date	0910060467/17/06/2014

Norms Committee Decision:

The Committee considered the request of the firm for enhancement of norms and it was observed that the firm had earlier represented its case for enhancement of norms and was called to attend Personal Hearing. The firm had attended the Personal Hearing in Meeting No. **NC/3/MEET/Apr/202223/2 dated 20.04.2022** and after hearing the explanation of the Representatives of firm, it was observed that the export description given in this Advance Authorization is not from non- infringing process. Moreover, it was also noted by the committee that the firm is a regular exporter of these pharma items but have not taken any licence under non- infringing clause directly from RA , as per the policy provision given under para 4.18 of HBP Vol. I. The Representative of firm also agreed with observation of the committee that the exports are being made under buy back arrangement. Accordingly, the request of firm was **rejected**.

Now, the firm has again requested for enhancement in the quantity of import items. In view of above, the Committee decided to **reject** the case maintaining the status quo.

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

Case No.	4 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002557AM23
RA File Number	039404000494 AM15
Licence No and Date	0310788620/02/09/2014

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms for Export Product after deliberation, it was decided to fix adhoc norms for Export Product No. 6 and 7 as under:

No. 6 and 7 and

Adhoc norms for Export Product No. 6 - Ozonol antibiotic 15 gm

Export Product	Qty.	Sl. No.	Import Items	Qty.
Ozonol antibiotic 15 gm	1 Number	1	WHITE PROTOPET	14.2584 gram
		2	LIDOCAINE HYDROCHLORIDE	0.612 gram
		3	BACITRACIN NON STERILE MICRONIZED	107.667 mg
		4	POLYMYXIN B SULPHATE (NON STER. MICRO)	0.02205 gram
		5	Alluminium collapsible tune 15 gms whether printed or out	Relevant, as per packing policy

Adhoc norms for Export Product No. 7 - Ozonol antibiotic 30 gm

Export Product	Qty.	Sl. No.	Import Items	Qty.
Ozonol antibiotic 30 gm	1 Number	1	WHITE PROTOPET	28.5168 gram
		2	LIDOCAINE HYDROCHLORIDE	1.224 gram
		3	BACITRACIN NON STERILE MICRONIZED	212.75 mg
		4	POLYMYXIN B SULPHATE (NON STER MICRO)	0.0441 gram
		5	Alluminium collapsible tune 30 gms whether printed or out	Relevant, as per packing policy

Rest of the earlier Minutes would remain the same.

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

Case No.	5 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002556AM23
RA File Number	039404000590 AM16
Licence No and Date	0310799952/02/11/2015
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and it was decided to revise adhoc norms as under:	

Export Product	Qty.	Sl. No.	Import Items	Qty.
Fusidic Acid Cream 15 Gm. Tube(Tech. Spec: Labelled content Fusidic Acid 2% W/W; Brand Amigermol Crema or any other.)	1 Number	1	Fusidic Acid Micronized	0.306 gram
		2	White Soft Paraffin (Petrolatium Jelly)	0.840 gram
		3	Liquid Paraffin (Mineral Oil Kyadol)	1.665 gram
		4	Empty Aluminium Tube 15 Gm. Printed	Relevant as per packing policy

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

Case No.	6 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002220AM23
RA File Number	072404000386 AM16
Licence No and Date	0710109429/23/02/2016

Norms Committee Decision:

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

Sl. No.	EXPORT PRODUCT	QTY.	Sl. No.	IMPORT ITEMS	QTY.
1	MAGNESIUM CITRATE	1 kg	1	CITRIC ACID	1.001 kg
			2	MAGNESIUM CARBONATE	0.730 kg
2	CALCIUM CITRATE	1 kg	1	CITRIC ACID	0.816 kg

			3	CALCIUM CARBONATE	0.660 kg
3	ZINC CITRATE	1 kg	1	CITRIC ACID	0.880 kg
4	POTASSIUM CITRATE	1 kg	1	CITRIC ACID	0.859 kg

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

Case No.	7 / NC/3/MEET/Oct/202223/11
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00001940AM23
RA File Number	092404000348 AM17
Licence No and Date	0910064196/28/09/2016
Norms Committee Decision: The Committee considered the request of the firm for enhancement of norms and it was observed that the firm had earlier represented its case for enhancement of norms and was called to attend Personal Hearing. The firm had attended the Personal Hearing in Meeting No. NC/3/MEET/Apr/202223/2 dated 20.04.2022 and after hearing the explanation of the Representatives of firm, it was observed that the export description given in this Advance Authorization is not from non- infringing process. Moreover, it was also noted by the committee that the firm is a regular exporter of these pharma items but have not taken any licence under non- infringing clause directly from RA , as per the policy provision given under para 4.18 of HBP Vol. I. The Representative of firm also agreed with observation of the committee that the exports are being made under buy back arrangement. Accordingly, the request of firm was rejected. Now, the firm has again requested for enhancement in the quantity of import items. In view of above, the Committee decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	8 / NC/3/MEET/Oct/202223/11
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00001941AM23
RA File Number	092404000649 AM17

Licence No and Date	0910064785/09/03/2017
Norms Committee Decision: The Committee considered the request of the firm for enhancement of norms and it was observed that the firm had earlier represented its case for enhancement of norms and was called to attend Personal Hearing. The firm had attended the Personal Hearing in Meeting No. NC/3/MEET/Apr/202223/2 dated 20.04.2022 and after hearing the explanation of the Representatives of firm, it was observed that the export description given in this Advance Authorization is not from non- infringing process. Moreover, it was also noted by the committee that the firm is a regular exporter of these pharma items but have not taken any licence under non- infringing clause directly from RA , as per the policy provision given under para 4.18 of HBP Vol. I. The Representative of firm also agreed with observation of the committee that the exports are being made under buy back arrangement. Accordingly, the request of firm was rejected. Now, the firm has again requested for enhancement in the quantity of import items. In view of above, the Committee decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	9 / NC/3/MEET/Oct/202223/11
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00000968AM23
RA File Number	092404000309 AM18
Licence No and Date	0910065528/29/09/2017
Norms Committee Decision: The Committee considered the request of the firm for enhancement of norms and it was observed that the firm had earlier represented its case for enhancement of norms and was called to attend Personal Hearing. The firm had attended the Personal Hearing in Meeting No. NC/3/MEET/Apr/202223/2 dated 20.04.2022 and after hearing the explanation of the Representatives of firm, it was observed that the export description given in this Advance Authorization is not from non- infringing process. Moreover, it was also noted by the committee that the firm is a regular exporter of these pharma items but have not taken any licence under non- infringing clause directly from RA , as per the policy provision given under para 4.18 of HBP Vol. I. The Representative of firm also agreed with observation of the committee that the exports are being made under buy back arrangement. Accordingly, the request of firm was rejected. Now, the firm has again requested for enhancement in the quantity of import items. In view of above, the Committee decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	10 / NC/3/MEET/Oct/202223/11
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00001945AM23
RA File Number	092404000430 AM18
Licence No and Date	0910065723/07/12/2017
Norms Committee Decision: T The Committee considered the request of the firm for enhancement of norms and it was observed that the firm had earlier represented its case for enhancement of norms and was called to attend Personal Hearing. The firm had attended the Personal Hearing in Meeting No. NC/3/MEET/Apr/202223/2 dated 20.04.2022 and after hearing the explanation of the Representatives of firm, it was observed that the export description given in this Advance Authorization is not from non- infringing process. Moreover, it was also noted by the committee that the firm is a regular exporter of these pharma items but have not taken any licence under non- infringing clause directly from RA , as per the policy provision given under para 4.18 of HBP Vol. I. The Representative of firm also agreed with observation of the committee that the exports are being made under buy back arrangement. Accordingly, the request of firm was rejected. Now, the firm has again requested for enhancement in the quantity of import items. In view of above, the Committee decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	11 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00001131AM23
RA File Number	052304000334 AM18
Licence No and Date	0510404915/13/12/2017
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Dec/202122/12 dated 17.12.2021 against advance authorization No. 0510409477 dated 25.01.2019 and 0510411049 dated 25.06.2019, it was decided to revise adhoc norms as under:	

Export product	Qty.	Sl. No.	Import items	Qty.
DI-BUTYL PHTHALATE (GRADE-M) (DBP-M) ((PACKED IN 2554 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES (21,709.000 KGS. WITHOUT WASTAGE)) (EACH DRUM SHALL WEIGHT 8.5 KG AND STORAGE CAPACITY 235.000 KGS.))	1 kg	1	PHTHALIC ANHYDRIDE	0.56 kg
		2	SABUTOL	0.595 kg
		3	HDPE GRANULES	Relevant as per packing policy

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

Case No.	12 / NC/3/MEET/Oct/202223/11
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00000970AM23
RA File Number	092404000459 AM18
Licence No and Date	0910065758/19/12/2017
Norms Committee Decision: The Committee considered the request of the firm for enhancement of norms and it was observed that the firm had earlier represented its case for enhancement of norms and was called to attend Personal Hearing. The firm had attended the Personal Hearing in Meeting No. NC/3/MEET/Apr/202223/2 dated 20.04.2022 and after hearing the explanation of the Representatives of firm, it was observed that the export description given in this Advance Authorization is not from non- infringing process. Moreover, it was also noted by the committee that the firm is a regular exporter of these pharma items but have not taken any licence under non- infringing clause directly from RA , as per the policy provision given under para 4.18 of HBP Vol. I. The Representative of firm also agreed with observation of the committee that the exports are being made under buy back arrangement. Accordingly, the request of firm was rejected. Now, the firm has again requested for enhancement in the quantity of import items. In view of above, the Committee decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	13 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SHREE GANESH REMEDIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002092AM23
RA File Number	342404000340 AM18
Licence No and Date	3410043947/09/03/2018
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information/documents from the firm: i. Complete set of 4.07 application. ii. Complete technical details as per Annexure to Appendix 4E. iii. Stoichiometric balance.	

Case No.	14 / NC/3/MEET/Oct/202223/11
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00000969AM23
RA File Number	092404000036 AM19
Licence No and Date	0910066244/18/05/2018
Norms Committee Decision: The Committee considered the request of the firm for enhancement of norms and it was observed that the firm had earlier represented its case for enhancement of norms and was called to attend Personal Hearing. The firm had attended the Personal Hearing in Meeting No. NC/3/MEET/Apr/202223/2 dated 20.04.2022 and after hearing the explanation of the Representatives of firm, it was observed that the export description given in this Advance Authorization is not from non- infringing process. Moreover, it was also noted by the committee that the firm is a regular exporter of these pharma items but have not taken any licence under non- infringing clause directly from RA , as per the policy provision given under para 4.18 of HBP Vol. I. The Representative of firm also agreed with observation of the committee that the exports are being made under buy back arrangement. Accordingly, the request of firm was rejected. Now, the firm has again requested for enhancement in the quantity of import items. In view of above, the Committee decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	15 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002046AM23
RA File Number	082404000264 AM19
Licence No and Date	0810143988/29/11/2018
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was observed that the firm was earlier given PH through Video Conferencing in Meeting No. NC/3/MEET/Apr/202223/2 on 21.04.2022 for the reasonability of import item Nos. 2 and 3, i.e., Gelatin NF and Glycerine USP for export of Soft Gelatin Capsules. During PH, the firm could not be able to explain the technical issues, hence import item No. 2 and 3 were not recommended. Now, the firm has again requested and furnished some technical documents like Batch Formula, Batch Record and copies of confidential documents submitted to ANDA. Going through the documents now, it was felt that the firm may be given another chance for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	16 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	MALLADI DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00001752AM23
RA File Number	042404000218 AM19
Licence No and Date	0410165065/04/01/2019
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was observed that the norms applied by the firm are higher than supported by the chemistry and material balance. Also, the Export Product is a new molecule. Hence, it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	17 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SHREE GANESH REMEDIES LIMITED
Meeting Number	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022

and Date	
HQ File Number	HQRNORM REVIW00002113AM23
RA File Number	342404000399 AM19
Licence No and Date	3410045006/28/03/2019
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information/documents from the firm: i. Complete set of 4.07 application. ii. Complete technical details as per Annexure to Appendix 4E. iii. Stoichiometric balance.	

Case No.	18 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SYMBIOSIS PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00000804AM23
RA File Number	332404000002 AM20
Licence No and Date	3310030527/16/04/2019
Norms Committee Decision: Deferred for comments of TE.	

Case No.	19 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002204AM23
RA File Number	052304000048 AM20
Licence No and Date	0510410475/03/05/2019
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith following documents / information: i. DML. ii. COA of import item from foreign supplier. iii. Master Batch Formula.	

Case No.	20 / NC/3/MEET/Oct/202223/11
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00000971AM23
RA File Number	092404000269 AM20
Licence No and Date	0910067906/20/08/2019
Norms Committee Decision: The Committee considered the request of the firm for enhancement of norms and it was observed that the firm had earlier represented its case for enhancement of norms and was called to attend Personal Hearing. The firm had attended the Personal Hearing in Meeting No. NC/3/MEET/Apr/202223/2 dated 20.04.2022 and after hearing the explanation of the Representatives of firm, it was observed that the export description given in this Advance Authorization is not from non- infringing process. Moreover, it was also noted by the committee that the firm is a regular exporter of these pharma items but have not taken any licence under non- infringing clause directly from RA , as per the policy provision given under para 4.18 of HBP Vol. I. The Representative of firm also agreed with observation of the committee that the exports are being made under buy back arrangement. Accordingly, the request of firm was rejected. Now, the firm has again requested for enhancement in the quantity of import items. In view of above, the Committee decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	21 / NC/3/MEET/Oct/202223/11			
Case Status	Case Approved			
Party Name	GLOBAL CALCIUM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022			
HQ File Number	HQRNORM REVIW00002537AM23			
RA File Number	072404000107 AM20			
Licence No and Date	0710115314/21/08/2019			
Norms Committee Decision:				
The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

MINOXIDIL (USP / Ph.Eur / IP)	1 kg	1	2,4 DIAMINO-6-CHLOROPYRIMIDINE	0.95 kg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	22 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002536AM23
RA File Number	072404000117 AM20
Licence No and Date	0710115318/22/08/2019

Norms Committee Decision:

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

Sl. No.	Export product	Qty.
1	MINOXIDIL (IP/USP/Ph.Eur.)	2.500 MT
2	MINOXIDIL SULPHATE	2.00 MT

Sl. No.	Import items	Qty.
1	2,4 DIAMINO-6-CHLOROPYRIMIDINE	4.275 MT

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

Case No.	23 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	MALLADI DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022

HQ File Number	HQRNORM REVIW00001751AM23
RA File Number	042404000089 AM20
Licence No and Date	0410166026/29/08/2019
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was observed that the norms applied by the firm are higher than supported by the chemistry and material balance. Also, the Export Product is a new molecule. Hence, it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	24 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	MENTHA AND ALLIED PRODUCTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	018205000763AM20
RA File Number	052404000375 AM20
Licence No and Date	0510412231/23/10/2019
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the reply furnished by the firm was not clear. Hence, it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith following document / information: Exact specification of Export and to link it with import item with COA of both import and export, to justify the same.	

Case No.	25 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	THINQ PHARMA-CRO LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002242AM23
RA File Number	039504000967 AM20
Licence No and Date	0310833909/06/01/2020
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and taking 1.20 mole of side-chain	

against 1 mole of export product, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
G-101 (All Trans Retinoic Acid, 1-Hydroxy-3,3-dimethyl-2-Butanone Ester)	1 kg	1	Tretinoin (All Trans Retinoic Acid)	1.00 kg
		2	1-Chloro Pinacolone	0.600 kg
		3	Cesium Carbonate	1.135 kg

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

Case No.	26 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LACTOSE (INDIA) LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002116AM23
RA File Number	039504001033 AM20
Licence No and Date	0310834414/23/01/2020
Norms Committee Decision: The Committee considered the request of the firm for fixation of adhoc norms and it was observed that the Representation received from the firm was incomplete and highly confusing due to various grades mentioned in their export and import items. In view of above, the Committee decided to visit Firm's Factory to gather requisite information for fixation of norms.	

Case No.	27 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002535AM23
RA File Number	072404000008 AM21
Licence No and Date	0710116344/17/04/2020

Norms Committee Decision:

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

Sl. No.	Export product	Qty.
1	MINOXIDIL (USP/Ph.EUR/IP)	3.500 MT
2	MINOXIDIL SULPHATE	7.500 MT

Sl. No.	Import items	Qty.
1	2,4 DIAMINO-6-CHLOROPYRIMIDINE	10.450 MT

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

Case No.	28 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002013AM23
RA File Number	039404000022 AM21
Licence No and Date	0310835878/25/04/2020

Norms Committee Decision:

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	FLUOCINOLONE ACE EAR DROPS 0.01% 20ML (Fluocinolone Acetonide 0.01%) (Net Wt. of FLUOCINOLONE ACETONIDE BP in 1100 Gms.)	500000 Number	1	FLUOCINOLONE ACETONIDE BP	1020 grams

2	FLUOCINOLONE ACE SCALP OIL 0.01% 118ML (Fluocinolone Acetonide 0.01% Topical Oil) (Net Wt. of FLUOCINOLONE ACETONIDE BP in 6490 Gms.)	500000 Number	1	FLUOCINOLONE ACETONIDE BP	6078 grams
3	FLUOCINOLONE ACE BODY OIL 0.01% 118ML (Fluocinolone Acetonide 0.01% Topical Oil) (Net Wt. of FLUOCINOLONE ACETONIDE BP in 1298 Gms.)	100000 Number	1	FLUOCINOLONE ACETONIDE BP	1203.6 grams

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

Case No.	29 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002534AM23
RA File Number	072404000046 AM21
Licence No and Date	0710116483/22/05/2020
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information/documents from the firm: i. As per manufacturing details, there is blending as such the details (such as name and quantity) of items which are blended. ii. Complete technical details as per Annexure to Appendix 4E.	

Case No.	30 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002538AM23
RA File Number	072404000053 AM21
Licence No and Date	0710116510/27/05/2020
Norms Committee Decision:	

The Committee considered the request of firm for fixation of adhoc norms and it was decided to call for following information/documents from the firm:

- i. **Complete technical details as per Annexure to Appendix 4E clearly indicating indigenous items.**
- ii. **As per manufacturing details, there id blending as such the details (such as name and quantity) of items which are blended.**
- iii. **Purity with moisture content of both import and export items.**
- iv. **Production / Consumption data for three year duly certified by CA.**

Case No.	31 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00001816AM23
RA File Number	052304000071 AM21
Licence No and Date	0510414611/13/07/2020

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202122/12 dated 17.12.2021** against advance authorization No. **0510409477 dated 25.01.2019 and 0510411049 dated 25.06.2019** it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
DI-BUTYL PHTHALATE (GRADE-M) (DBP-M)((PACKED IN 2554 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES (21,709.000 KGS. WITHOUT WASTAGE)) (EACH DRUM SHALL WEIGHT 8.5 KG AND STORAGE CAPACITY 235.000 KGS.))	1 kg	1	PHTHALIC ANHYDRIDE	0.56 kg
		2	SABUTOL	0.595 kg
		3	HDPE GRANULES	Relevant as per packing policy

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

Case No.	32 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002084AM23
RA File Number	039404000232 AM21
Licence No and Date	0310837216/15/07/2020
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was decided to call for following information / documents from the firm: i. Description of Export Product does not match with the DML. Please clarify.	

Case No.	33 / NC/3/MEET/Oct/202223/11			
Case Status	Case Approved			
Party Name	AMINES AND PLASTICIZERS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022			
HQ File Number	018205001625AM21			
RA File Number	039404000370 AM21			
Licence No and Date	0310838163/08/09/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

Case No.	34 / NC/3/MEET/Oct/202223/11			
Case Status	Case Deferred			
Party Name	VIBRANT PHARMACHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022			

HQ File Number	018205001663AM21
RA File Number	072404000163 AM21
Licence No and Date	0710117014/15/09/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	35 / NC/3/MEET/Oct/202223/11										
Case Status	Case Approved										
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD										
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022										
HQ File Number	018205001738AM21										
RA File Number	039404000504 AM21										
Licence No and Date	0310838842/13/10/2020										
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. 0311008190 dated 02.11.2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>1,3 DIMETHYLOL -5,5- DIMETHYL HYDANTOIN (DMDM HYDANTOIN 52%-55%) ASSAY 55% MAX BELGUARD DMDMH</td><td>1 kg</td><td>1</td><td>5,5 DIMETHYL HYDANTOIN ASSAY 99% MIN COLOUR PURE WHITE</td><td>0.382 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	1,3 DIMETHYLOL -5,5- DIMETHYL HYDANTOIN (DMDM HYDANTOIN 52%-55%) ASSAY 55% MAX BELGUARD DMDMH	1 kg	1	5,5 DIMETHYL HYDANTOIN ASSAY 99% MIN COLOUR PURE WHITE	0.382 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
1,3 DIMETHYLOL -5,5- DIMETHYL HYDANTOIN (DMDM HYDANTOIN 52%-55%) ASSAY 55% MAX BELGUARD DMDMH	1 kg	1	5,5 DIMETHYL HYDANTOIN ASSAY 99% MIN COLOUR PURE WHITE	0.382 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	36 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	SYNNAT PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	018205001771AM21
RA File Number	022404000094 AM21
Licence No and Date	0210210167/20/10/2020

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09.09.2022** against advance authorization No. **0210208260 dated 07.03.2018**, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Noscapine BP USP Ph.Eur JP CP / Noscapine Hydrochloride BP Ph.Eur	1 kg	1	Noscapine Crude Content 95%	1.158 kg

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

Case No.	37 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	018205001853AM21
RA File Number	342404000223 AM21
Licence No and Date	3410046549/13/11/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	38 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	THINQ PHARMA-CRO LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002241AM23
RA File Number	03AA04013380 AM21
Licence No and Date	0311000264/24/12/2020
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and taking 1.20 mole of side-chain against 1 mole of export product, it was decided to revise adhoc norms as under:	

Export product	Qty.	Sl. No.	Import items	Qty.
G-101 (All Trans Retinoic Acid, Hydroxy-3,3-dimethyl-2-Butanone Ester)	1-1 kg	1	Tretinoin (All Trans Retinoic Acid)	1.00 kg
		2	1-Chloro Pinacolone	0.600 kg
		3	Cesium Carbonate	1.135 kg

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

Case No.	39 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002081AM23
RA File Number	03AA04016798 AM21
Licence No and Date	0311000935/14/01/2021

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/9 dated 07.10.2022** against advance authorization No. **0311012331 dated 07.03.2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
2-AMINO-2-PHENYLBUTYRIC ACID SODIUM SALT (SATURATED ACYCLIC MONOCARBOXYLIC ACIDS & THEIR SALTS)	1 kg	1	PROPIOPHENONE	0.922 kg
		2	SODIUM CYANIDE	0.337 kg

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

Case No.	40 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002205AM23
RA File Number	03AA04021752 AM21
Licence No and Date	0311001487/04/02/2021
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and following things were observed: i. Firm has revised the import quantity. ii. Wastage applied 8% for Topical Solution involving 5-6% overfilling. iii. Firm has given Batch Record to Show API requirement and Excipients. Hence, it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	41 / NC/3/MEET/Oct/202223/11
Case Status	Case Rejected
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002258AM23
RA File Number	07AA04009852 AM21
Licence No and Date	0711000657/15/03/2021
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was observed Rubber Stopper is already allowed as per General Policy for Packing Material mentioned in Handbook of Procedure Vol. II (SION Book). Hence, it was decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	42 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	VIBRANT PHARMACHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00000295AM22
RA File Number	07AA04011201 AM21
Licence No and Date	0711000825/01/04/2021
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	43 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00000680AM22
RA File Number	30AA04006198 AM21
Licence No and Date	3011000463/01/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: i. Percentage yield on molar basis for each step of manufacturing process. ii Stepwise material balance sheet based on the recent batch record.	

Case No.	44 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00023689AM22
RA File Number	07AA04002023 AM22
Licence No and Date	0711000922/21/04/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	45 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00027802AM22
RA File Number	07AA04002553 AM22
Licence No and Date	0711000992/27/04/2021
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	46 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00027804AM22
RA File Number	07AA04002549 AM22
Licence No and Date	0711000993/27/04/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	47 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00027780AM22
RA File Number	07AA04000758 AM22
Licence No and Date	0711000991/27/04/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: i. Production / Consumption data of export product MAGNESIUM BISGLYCINATE / MAGNESIUM GLYCINE COMPLEX(MAGNESIUM BISGLYCINATE / MAGNESIUM GLYCINE COMPLEX)MAGNESIUM GLYCINE COMPLEX) for the years 2018-19 and 2019-20 duly certified by GST. ii COA report of Magnesium Oxide.	

Case No.	48 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00028506AM22
RA File Number	07AA04002556 AM22
Licence No and Date	0711001000/28/04/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
ALPRAZOLAM (IP/BP/EP/USP)	1 kg	1	TRIETHYL ORTHO ACETATE	1.108 kg
		2	ACETONE	1.50 kg

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

Case No.	49 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00029824AM22
RA File Number	03AA04003827 AM22
Licence No and Date	0311003447/30/04/2021

Norms Committee Decision:

The Committee considered the case as per agenda and it was observed that the reply furnished by the firm was not clear. Hence, it was decided to call the firm for attending **Personal Hearing** before Norms Committee to explain its case.

Case No.	50 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	CLARIANT INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00032203AM22
RA File Number	03AA04009823 AM22
Licence No and Date	0311003530/04/05/2021

Norms Committee Decision:

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

- i. Reason for not indicating indigenous items in Appendix 4E.
- ii. Large difference in individual yield and actual output, therefore complete justification for low yield.
- iii Reason for non-recovery of methanol in the process.

Case No.	51 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00033515AM22
RA File Number	05AA04007697 AM22
Licence No and Date	0511002442/05/05/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking into consideration 83% yield, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
2,2-difluoro-1,3-benzodioxole(DFBD)	1 kg	1	BENZOTRIFLUORIDE (BTF)	0.16 kg
		2	1,3-BENZODIOXOLE	0.9306 kg

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

Case No.	52 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00036355AM22
RA File Number	03AA04007493 AM22
Licence No and Date	0311003675/09/05/2021

Norms Committee Decision:

Deferred for comments of TE.

Case No.	53 / NC/3/MEET/Oct/202223/11
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Case Status	Case Deferred
Party Name	SHREE GANESH REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002093AM23
RA File Number	34AA04000586 AM22
Licence No and Date	3411000551/11/05/2021
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information/documents from the firm: i. Complete set of 4.07 application. ii. Complete technical details as per Annexure to Appendix 4E. iii. Stoichiometric balance	

Case No.	54 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	MACLEODS PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00038818AM22
RA File Number	03AA04005126 AM22
Licence No and Date	0311003736/12/05/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	55 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00045345AM22
RA File Number	30AA04001247 AM22
Licence No and Date	3011000633/18/05/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:	

i. Percentage yield on molar basis for each step of manufacturing process.

ii Stepwise material balance based on the recent batch record.

Case No.	56 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	UNITED MUD-CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00103082AM22
RA File Number	03AA04017853 AM22
Licence No and Date	0311004136/30/05/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
RHEOLOGY MODIFIER (containing 79.61% Dimer Acid)	60 MT	1	Dimer Acid	48.24 MT

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

Case No.	57 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00107290AM22
RA File Number	34AA04002205 AM22
Licence No and Date	3411000694/04/06/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
Gamma - Decalactone	100000 kg	1	Acrylic Acid	83843.00 kg
		2	Di tert Butyl Peroxide	31000.00 kg

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

Case No.	58 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00107366AM22
RA File Number	34AA04002212 AM22
Licence No and Date	3411000697/04/06/2021

Norms Committee Decision:

The Committee considered the case as per agenda and on the basis of information provided by the firm and taking commercial value of By-Product, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Gamma Undecalactone (Aldehyde C14)	100000 kg	1	Acrylic Acid	84285.00 kg
		2	Di tert Butyl Peroxide	25000.00 kg

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

Case No.	59 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00108212AM22

RA File Number	05AA04019922 AM22
Licence No and Date	0511002989/05/06/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	60 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00109187AM22
RA File Number	03AA04022509 AM22
Licence No and Date	0311004402/07/06/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09.09.2022** against advance authorization No. **0210208260 dated 07.03.2018**, it was decided to revise adhoc norms as under:

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

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

Case No.	61 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00109628AM22
RA File Number	03AA04019238 AM22
Licence No and Date	0311004420/08/06/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that it was not possible to correlate import item Nos. 2 to 8 with the export product. Hence, it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith sample of import items.	

Case No.	62 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00109428AM22
RA File Number	34AA04002141 AM22
Licence No and Date	3411000701/08/06/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. 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. Stoichiometric balance between import and export on molar basis. iv. Complete justification of wastage of raw materials for the manufacturing of export product.	

Case No.	63 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00109478AM22
RA File Number	09AA04003622 AM22
Licence No and Date	0911001018/08/06/2021
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jun/202223/5 dated 08.07.2022** against advance authorization No. **0910069429 dated 03.11.2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export Product	Qty.	Sl. No.	Import items	Qty.
Ashton & Parson Infant Powders((Each Sachet Contains - 4.055 Mg of Tincture Matricaria Duplex))	1 Number Sachet	1	Tincture Matricaria Duplex	4.136 mg
		2	Lactose Monohydrate modified	259.62 mg

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

Case No.	64 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	THINQ PHARMA-CRO LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002243AM23
RA File Number	03AA04053651 AM22
Licence No and Date	0311005719/29/07/2021

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and as per GST given for 1.28 kg/kg during 2020-21 and averaging the earlier ratified norms with GST data, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Dimethyl Isosorbide	1 kg	1	Isosorbide	1.10 kg

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

Case No.	65 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred

Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM REVIW00002321AM23
RA File Number	03AA040118606 AM22
Licence No and Date	0311008613/16/11/2021
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information/documents from the firm: i. Copy of DML for export. ii. Composition of export product showing percentage content of API and Buffering Agent. iii COA of export product.	

Case No.	66 / NC/3/MEET/Oct/202223/11																			
Case Status	Case Approved																			
Party Name	ELIXIR PHARMA																			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022																			
HQ File Number	HQRNORM APPLY 00262257AM22																			
RA File Number	08AA04034885 AM22																			
Licence No and Date	0811003200/23/11/2021																			
Norms Committee Decision:																				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Apr/202223/1 dated 29.04.2022 against advance authorization No. 0811002031 dated 19.07.2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:																				
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="3">3-ISOBUTYL GLUTARIC ACID (CMH DIACID)</td><td rowspan="3">1 kg</td><td>1</td><td>ISOVALERALDEHYDE</td><td>0.6068 kg</td></tr><tr><td>2</td><td>ETHYL CYANOACETATE</td><td>0.7814 kg</td></tr><tr><td>3</td><td>DIETHYL MALONATE</td><td>0.90 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	3-ISOBUTYL GLUTARIC ACID (CMH DIACID)	1 kg	1	ISOVALERALDEHYDE	0.6068 kg	2	ETHYL CYANOACETATE	0.7814 kg	3	DIETHYL MALONATE	0.90 kg
Export product	Qty.	Sl. No.	Import items	Qty.																
3-ISOBUTYL GLUTARIC ACID (CMH DIACID)	1 kg	1	ISOVALERALDEHYDE	0.6068 kg																
		2	ETHYL CYANOACETATE	0.7814 kg																
		3	DIETHYL MALONATE	0.90 kg																

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

Case No.	67 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00262416AM22
RA File Number	34AA04008408 AM22
Licence No and Date	3411001440/23/11/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:	
i. By-Product obtained during the reaction for manufacturing of export item giving its value with invoices.	

Case No.	68 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00262423AM22
RA File Number	05AA04098088 AM22
Licence No and Date	0511006367/23/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	69 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00263483AM22
RA File Number	03AA04003343 AM22
Licence No and Date	0311008815/24/11/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	

- i. **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.**

Case No.	70 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00263486AM22
RA File Number	03AA04009051 AM22
Licence No and Date	0311008816/24/11/2021

Norms Committee Decision:

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

- i. **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.**

Case No.	71 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00263488AM22
RA File Number	03AA04014060 AM22
Licence No and Date	0311008817/24/11/2021

Norms Committee Decision:

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

- i. **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.**

Case No.	72 / NC/3/MEET/Oct/202223/11													
Case Status	Case Approved													
Party Name	SENTISS PHARMA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022													
HQ File Number	HQRNORM APPLY 00265259AM22													
RA File Number	05AA040104139 AM22													
Licence No and Date	0511006448/25/11/2021													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/May/202223/4 dated 17.06.2022 against advance authorization No. 0511002009 dated 31.03.2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<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>Brimonidine Tartrate 0.1 Percent Eye Drops Solution 5ml Santabrim</td> <td>166667 Vials</td> <td>1</td> <td>Brimonidine Tartrate</td> <td>0.85 kg</td> </tr> </tbody> </table>					Export product	Qty.	Sl. No.	Import items	Qty.	Brimonidine Tartrate 0.1 Percent Eye Drops Solution 5ml Santabrim	166667 Vials	1	Brimonidine Tartrate	0.85 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Brimonidine Tartrate 0.1 Percent Eye Drops Solution 5ml Santabrim	166667 Vials	1	Brimonidine Tartrate	0.85 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	73 / NC/3/MEET/Oct/202223/11			
Case Status	Case Approved			
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022			
HQ File Number	HQRNORM APPLY 00264884AM22			
RA File Number	03AA040120003 AM22			
Licence No and Date	0311008832/25/11/2021			
Norms Committee Decision:				

The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09.09.2022** against advance authorization No. **0310822175 dated 06.07.2018**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	OXYBUTYNIN CHLORIDE EXTENDED RELEASE TAB USP 5 MG. Each tablet contains (i) Oxybutynin Chloride USP- 5 mg (ii) Eastman((TM Cellulose Acetate (CA 398-10NF/EP)- 38.88 mg (iii) Sentry Polyox WSR N80 FP NF- 80.52 mg (iv) Sentry Polyox WSR 303 NF- 41.10 mg. Net content (i) 68.808 Kgs (ii) 535.05 Kgs (iii) 1108.08 Kgs (iv) 565.60 Kgs.)	1 Number	1	OXYBUTYNIN CHLORIDE USP	5.10 mg
			2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	38.88 mg
			3	SENTRY POLYOX WSR N80 FP NF	80.52 mg
			4	SENTRY POLYOX WSR 303 NF	41.10 mg
2	OXYBUTYNIN CHLORIDE EXTENDED RELEASE TAB. USP 10 MG. Each tablet contains (i) Oxybutynin Chloride USP- 10mg (ii) Eastman((TM Cellulose Acetate (CA 398-10NF/EP)- 38.88 mg (iii) Sentry Polyox WSR N80 FP NF- 80.77 mg (iv) Sentry Polyox WSR 303 NF- 41.10 mg. Net content (i) 68.807 Kgs (ii) 267.52 Kgs (iii) 555.754 Kgs (iv) 282.80 Kgs.)	1 Number	5	OXYBUTYNIN CHLORIDE USP	10.20 mg
			6	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	38.88 mg
			7	SENTRY POLYOX WSR N80 FP NF	80.77 mg
			8	SENTRY POLYOX WSR 303 NF	41.10 mg
3	OXYBUTYNIN CHLORIDE	1 Number	9	OXYBUTYNIN CHLORIDE USP	15.30 mg

EXTENDED RELEASE TAB. USP 15 MG. Each tablet contains (i) Oxybutynin Chloride USP - 15 mg(ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 38.88 mg (iii) Sentry Polyox WSR N80 FP NF- 81.02 mg (iv) Sentry Polyox WSR 303 NF- 41.10 mg. Net content (i) 91.743 Kgs (ii) 237.798 Kgs (iii) 495.535 Kgs (iv) 251.376 Kgs.)	10	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	38.88 mg
	11	SENTRY POLYOX WSR N80 FP NF	81.02 mg
	12	SENTRY POLYOX WSR 303 NF	41.10 mg

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

Case No.	74 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00266181AM22
RA File Number	08AA04035102 AM22
Licence No and Date	0811003242/26/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	75 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LAZERHEAD LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00266328AM22
RA File Number	09AA04012424 AM22
Licence No and Date	0911001950/26/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	76 / NC/3/MEET/Oct/202223/11
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Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00268778AM22
RA File Number	09AA04017927 AM22
Licence No and Date	0911001956/29/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	77 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00268952AM22
RA File Number	03AA040120475 AM22
Licence No and Date	0311009010/29/11/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Apr/202223/1 dated 29.04.2022** against advance authorization No. **0311009726 dated 23.12.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Doxycycline Hyclate DR Tablets USP 75 mg , 100'S US((1,450 Bottles X 100 Per Bottles = 1,45,000 Tablets) (Total Weight of Export Product = 10.88 Kgs) (Net Content weight of Import Product = 12.88 kgs))	145000 Tablets	1	Doxycycline Hyclate USP	12.55 kg
2	Export Item Name: Doxycycline Hyclate DR Tablets USP 100 mg , 100'S US((9,900 Bottles X 100 Per Bottles = 9,90,000 Tablets) (Total Weight of Export Product = 99.00 Kgs) (Net Content weight of Import Product = 117.28 kgs))	990000 Tablets	2	Doxycycline Hyclate USP	114.25 kg

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

Case No.	78 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00270155AM22
RA File Number	342404000285 AM20
Licence No and Date	3411001477/30/11/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: i. Copy of DML for export item. ii Complete chemistry, molecular weight, percentage yield on molar basis etc. as per Annexure to Appendix 4E.	

Case No.	79 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00271471AM22
RA File Number	342404000079 AM21
Licence No and Date	3411001482/01/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: i. Copy of DML for export item. ii Complete chemistry, molecular weight, percentage yield on molar basis etc. as per Annexure to Appendix 4E.	

Case No.	80 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022

and Date	
HQ File Number	HQRNORM APPLY 00271583AM22
RA File Number	342404000002 AM21
Licence No and Date	3411001484/01/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis. Details of indigenous input with quantity.	

Case No.	81 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00271633AM22
RA File Number	342404000080 AM21
Licence No and Date	3411001485/01/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis. Details of indigenous input with quantity.	

Case No.	82 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	UPL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00271160AM22
RA File Number	03AA040125862 AM22

Licence No and Date	0311009068/01/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	83 / NC/3/MEET/Oct/202223/11													
Case Status	Case Approved													
Party Name	NEXUS PHARMA CHEM PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022													
HQ File Number	HQRNORM APPLY 00271316AM22													
RA File Number	08AA04035774 AM22													
Licence No and Date	0811003272/01/12/2021													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Aug/202223/6 dated 09.09.2022 against advance authorization No. 0811003688 dated 06.01.2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Clobetasol Propionate USP</td><td>1 kg</td><td>1</td><td>Betamethasone base</td><td>1.00 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	Clobetasol Propionate USP	1 kg	1	Betamethasone base	1.00 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Clobetasol Propionate USP	1 kg	1	Betamethasone base	1.00 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	84 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00272097AM22
RA File Number	07AA04040799 AM22
Licence No and Date	0711002516/02/12/2021
Norms Committee Decision:	
The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Sl. No.	Export product	Qty.
1	MINOXIDIL (USP/Ph.EUR/IP)	9.00 MT
2	MINOXIDIL SULPHATE	7.00 MT

Sl. No.	Import items	Qty.
1	2,4 DIAMINO -6-CHLOROPYRIMIDINE	15.66855 MT

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

Case No.	85 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00272098AM22
RA File Number	07AA04040797 AM22
Licence No and Date	0711002517/02/12/2021

Norms Committee Decision:

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

i. Production / Consumption data of export product MAGNESIUM BISGLYCINATE / MAGNESIUM GLYCINE COMPLEX(MAGNESIUM BISGLYCINATE / MAGNESIUM GLYCINE COMPLEX)MAGNESIUM GLYCINE COMPLEX) for the years 2018-19 and 2019-20 duly certified by GST.

ii COA report of Magnesium Oxide.

Case No.	86 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	YASHO INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00272724AM22
RA File Number	03AA04012775 AM22
Licence No and Date	0311009114/02/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the reply furnished by the firm was incomplete. Hence, it was decided to call for following information/documents from the firm: i. Stoichiometric balance to arrive at the quantity of raw material asked for. ii Percentage yield of reaction in first stage.	

Case No.	87 / NC/3/MEET/Oct/202223/11			
Case Status	Case Approved			
Party Name	GLOBAL CALCIUM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022			
HQ File Number	HQRNORM APPLY 00272084AM22			
RA File Number	07AA04039101 AM22			
Licence No and Date	0711002507/02/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

Case No.	88 / NC/3/MEET/Oct/202223/11			
Case Status	Case Approved			
Party Name	AMARA LABS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022			
HQ File Number	HQRNORM APPLY 00272745AM22			

RA File Number	09AA04018011 AM22			
Licence No and Date	0911001982/02/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
N Methyl Loratadine(N Methyl Loratadine)	1 kg	1	Meta Chloro Benzyl Cyanide	1.37 kg
		2	N N Dimethyl Carbomyl Chloride	0.68 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	89 / NC/3/MEET/Oct/202223/11			
Case Status	Case Approved			
Party Name	GLOBAL CALCIUM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022			
HQ File Number	HQRNORM APPLY 00272085AM22			
RA File Number	07AA04039096 AM22			
Licence No and Date	0711002508/02/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. 4/82-ALC4/2019 dated 19.07.2019 against advance authorization No. 0710109416 dated 18.02.2016 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
CALCIUM LACTATE GLUCONATE	1 kg	1	CALCIUM LACTATE PENTAHYDRATE	0.490 kg
		2	CALCIUM GLUCONATE	0.680 kg

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

Case No.	90 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	PMC RUBBER CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00272783AM22
RA File Number	02AA04035173 AM22
Licence No and Date	0211001583/02/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. COA of catalogue of import and export item. ii Net content of import item in export product.	

Case No.	91 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00272089AM22
RA File Number	07AA04039105 AM22
Licence No and Date	0711002509/02/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: i. Production / Consumption data of export product L-ORNITHINE-L-ASPARTATE (PURE-PHARMA) for the years 2018-19 and 2019-20 duly certified by GST. ii Complete justification of wastage of raw materials for the manufacturing of export product.	

Case No.	92 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00272834AM22
RA File Number	03AA04014502 AM22
Licence No and Date	0311009117/02/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis Details of indigenous input with quantity.	

Case No.	93 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00272093AM22
RA File Number	07AA04040783 AM22
Licence No and Date	0711002512/02/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jun/202122/2 dated 02.07.2021 against advance authorization No. 0711000943 dated 23.04.2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

	LACTOBIONATE		2	CALCIUM CARBONATE	0.360 kg
			3	HYDROBROMIC ACID	0.510 kg
3	CALCIUM GLUBIONATE	1 kg	1	LACTOSE	0.829 kg
			2	CALCIUM CARBONATE	0.140 kg
			3	CALCIUM GLUCONATE	0.42 kg
4	LACTOBIONIC ACID	1 kg	1	LACTOSE	0.5071 kg
			2	CALCIUM CARBONATE	0.0738 kg

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

Case No.	94 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00272951AM22
RA File Number	03AA04014150 AM22
Licence No and Date	0311009127/02/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. 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.	

Case No.	95 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00272095AM22
RA File Number	07AA04040782 AM22
Licence No and Date	0711002513/02/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jun/202122/2 dated 02.07.2021** against advance authorization No. **0711000943 dated 23.04.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	CALCIUM LACTOBIONATE	1 kg	1	LACTOSE	1.16 kg
			2	CALCIUM CARBONATE	0.17 kg
2	CALCIUM BROMO LACTOBIONATE	1 kg	1	LACTOSE	1.021 kg
			2	CALCIUM CARBONATE	0.360 kg
			3	HYDROBROMIC ACID	0.510 kg
3	CALCIUM GLUBIONATE	1 kg	1	LACTOSE	0.829 kg
			2	CALCIUM CARBONATE	0.140 kg
			3	CALCIUM GLUCONATE	0.42 kg
4	LACTOBIONIC ACID	1 kg	1	LACTOSE	1.58 kg
			2	CALCIUM CARBONATE	0.234 kg

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

Case No.	96 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	PUNJAB CHEMICALS AND CROP PROTECTION LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00274052AM22
RA File Number	03AA040121338 AM22
Licence No and Date	0311009169/03/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jun/202223/5 dated 08.07.2022** against advance authorization No. **0311001236 dated 28.01.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
TRIMETHYL SULFOXONIUM BROMIDE	1 kg	1	DIMETHYL SULFOXIDE	0.932 kg
		2	TRIMETHYL ORTHOFORMATE	0.018 kg

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

Case No.	97 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	PUNJAB CHEMICALS AND CROP PROTECTION LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00274069AM22
RA File Number	03AA040121871 AM22
Licence No and Date	0311009171/03/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jun/202223/5 dated 08.07.2022** against advance authorization No. **0311001236 dated 28.01.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
TRIMETHYL SULFOXONIUM BROMIDE	1 kg	1	DIMETHYL SULFOXIDE	0.932 kg
		2	TRIMETHYL ORTHOFORMATE	0.018 kg

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

Case No.	98 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00273476AM22
RA File Number	34AA04009751 AM22
Licence No and Date	3411001491/03/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and on the basis of information provided by the firm and taking commercial value of By-Product, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Gamma Undecalactone (Aldehyde C14)	200000 kg	1	Acrylic Acid	168570.00 kg
		2	Di tert Butyl Peroxide	50000.00 kg

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

Case No.	99 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	RAKSHIT PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022

HQ File Number	HQRNORM APPLY 00276086AM22
RA File Number	09AA04016769 AM22
Licence No and Date	0911002001/06/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	100 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00276162AM22
RA File Number	03AA040123869 AM22
Licence No and Date	0311009212/06/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:	
i. DML for each export product. ii. Master Batch Formula for each export product.	

Case No.	101 / NC/3/MEET/Oct/202223/11				
Case Status	Case Approved				
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022				
HQ File Number	HQRNORM APPLY 00276913AM22				
RA File Number	05AA040105427 AM22				
Licence No and Date	0511006662/06/12/2021				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Citicoline Tablets 500mg,((Each Tablet contains Citicoline Sodium equivalent to	1 Number	1	Citicoline Sodium	523.60 mg

	Citicoline 500mg) (Equivalent to bulk drug of 1190 Kg))				
2	Export Item Name: Citicoline Injection 250mg/ml, 2 ml Ampoule((Each 2ml Injection contains Citicoline Sodium equivalent to Citicoline	1 Number	2	Citicoline Sodium	573.00 mg
3	Citicoline Injection 250mg/ml, 4 ml Ampoule((Each 4ml Injection contains Citicoline Sodium equivalent to Citicoline 1gm) (Equivalent to bulk drug of 10.000 Kg) Total Bulk Drug Qty. 1205.00Kg.)	1 Number	3	Citicoline Sodium	1146.00 mg

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

Case No.	102 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00276997AM22
RA File Number	30AX04000001 AM22
Licence No and Date	3011001471/06/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	103 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	AURA PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00277561AM22
RA File Number	03AA040123116 AM22
Licence No and Date	0311009243/07/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	104 / NC/3/MEET/Oct/202223/11
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Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00277912AM22
RA File Number	05AA040108247 AM22
Licence No and Date	0511006681/07/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	105 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00279887AM22
RA File Number	09AA04018537 AM22
Licence No and Date	0911002024/08/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	106 / NC/3/MEET/Oct/202223/11										
Case Status	Case Approved										
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022										
HQ File Number	HQRNORM APPLY 00281870AM22										
RA File Number	05AX04000039 AM22										
Licence No and Date	0511006799/10/12/2021										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jun/202223/5 dated 08.07.2022 against advance authorization No. 0511001102 dated 04.02.2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Ciprofloxacin and Dexamethasone</td><td>1 Number Bottle</td><td>1</td><td>Ciprofloxacin</td><td>26.22 mg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Ciprofloxacin and Dexamethasone	1 Number Bottle	1	Ciprofloxacin	26.22 mg
Export product	Qty.	Sl. No.	Import items	Qty.							
Ciprofloxacin and Dexamethasone	1 Number Bottle	1	Ciprofloxacin	26.22 mg							

Sterile Otic Suspension 7.5ml((Each ml contains Ciprofloxacin 3mg. & Dexamethasone 1mg (Equivalent to 14.625 Kg. Ciprofloxacin and 4.875 Kg. Dexamethasone Bulk Drug))		2	Dexamethasone USP (Micronised)	7.87 mg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	107 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00283907AM22
RA File Number	09AX04000009 AM22
Licence No and Date	0911002042/13/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	108 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00284396AM22
RA File Number	05AX04000058 AM22
Licence No and Date	0511006831/13/12/2021

Norms Committee Decision:

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Meropenem Buffered (Meropenem Sod Carbonate Blend) Bulk Drug / Pharmacopeal Grade (Relevant Bulk Drug) (Each 1208 mg Buffered product contains NLT 1000 mg Meropenem on Anhydrous basis)	940 kg	1	(4R,5S,6S)-3-[[[(3S,5S)-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6-[(1R)-1-hydroxyethyl]-4methyl-7-oxo-1-azabicyclo	778.132 kg

2	Meropenem Injection 500mg ((Each vial contains Meropenem Sterile equivalent to anhydrous Meropenem Sodium Carbonate 500 mg (Equivalent to 990 Kg of bulk drug) Pharmaceutical Formulations / Standard Grade) (Each 1208 mg Buffered product contains NLT 1000 mg Meropenem on Anhydrous basis)	1800000 Numbers	2	(4R,5S,6S)-3-[[[(3S,5S)-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6-[(1R)-1-hydroxyethyl]-4methyl-7-oxo-1-azabicyclo	819.522 kg
3	Meropenem Injection 1 Gm((Each vial contains Meropenem Sterile equivalent to anhydrous Meropenem Sodium Carbonate 1Gm (Equivalent to 1650Kg of bulk drug) Pharmaceutical Formulations / Standard Grade) (Each 1208 mg Buffered product contains NLT 1000 mg Meropenem on Anhydrous basis)	1500000 Numbers	3	(4R,5S,6S)-3-[[[(3S,5S)-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6-[(1R)-1-hydroxyethyl]-4methyl-7-oxo-1-azabicyclo	1365.870 kg

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

Case No.	109 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00283711AM22
RA File Number	07AA04040751 AM22
Licence No and Date	0711002615/13/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information from the firm:	
i. Please specify the Grades of import items.	

Case No.	110 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00283764AM22
RA File Number	09AA04017426 AM22
Licence No and Date	0911001978/13/12/2021

Norms Committee Decision:

Deferred for comments of TE.

Case No.	111 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00283775AM22
RA File Number	07AA04040754 AM22
Licence No and Date	0711002620/13/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **7/82-ALC4/2019 dated 06.09.2019** against advance authorization No. **0710114740 d** **ated 02.04.2019**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	MAGNESIUM LACTATE GLUCONATE	1 kg	1	GLUCONO DELTA LACTONE	0.754 kg
2	ZINC GLUCONATE (Eur.Ph/USP)	1 kg	1	GLUCONO DELTA LACTONE	0.945 kg
3	MAGNESIUM GLUCONATE (Eur.Ph/USP)	1 kg	1	GLUCONO DELTA LACTONE	0.934 kg
4	POTASSIUM GLUCONATE (USP)	1 kg	1	GLUCONO DELTA LACTONE	0.930 kg
5	FERROUS GLUCONATE (BP/EP/USP)	1 kg	1	GLUCONO DELTA LACTONE	0.887 kg
6	MANGANESE GLUCONATE (Eur.Ph/USP)	1 kg	1	GLUCONO DELTA LACTONE	0.945 kg
7	CALCIUM MAGNESIUM LACTATE GLUCONATE	1 kg	1	GLUCONO DELTA LACTONE	0.830 kg

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

Case No.	112 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00283847AM22
RA File Number	03AX04000077 AM22
Licence No and Date	0311009414/13/12/2021

Norms Committee Decision:

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Maxigesic cold & flu Hot Drink 500mg/150mg Sachets (Paracetamol & Ibuprofen Sachets 500 mg & 150 mg)(Maxigesic cold & flu Hot Drink 500mg/150mg Sachets (Paracetamol & Ibuprofen Sachets 500 mg & 150 mg) No. of Sachets 300000.00 (Net content of Ibuprofen Lysine Salt IH API 76.95 kg))	1 Number	1	Ibuprofen Lysine Salt IH	258.88 mg
2	Maxigesic cold & flu Hot Drink 1000mg/300mg Sachets (Paracetamol & Ibuprofen Sachets 1000 mg & 300 mg)(Maxigesic cold & flu Hot Drink 1000mg/300mg Sachets (Paracetamol & Ibuprofen Sachets 1000 mg & 300 mg) No. of Sachets 200000.00 (Net content of Ibuprofen Lysine Salt IH API 102.60 kg))	1 Number	2	Ibuprofen Lysine Salt IH	517.77 mg

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

Case No.	113 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred

Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00283891AM22
RA File Number	09AA04018526 AM22
Licence No and Date	0911002040/13/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	114 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00283899AM22
RA File Number	09AX04000002 AM22
Licence No and Date	0911002041/13/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	115 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00285202AM22
RA File Number	09AA04017427 AM22
Licence No and Date	0911002053/14/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	116 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00286998AM22
RA File Number	31AX04000006 AM22
Licence No and Date	3111000788/15/12/2021

Norms Committee Decision:

Deferred for comments of TE.

Case No.	117 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00287478AM22
RA File Number	03AA040122138 AM22
Licence No and Date	0311009510/16/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	118 / NC/3/MEET/Oct/202223/11													
Case Status	Case Approved													
Party Name	KusuMa PharMa													
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022													
HQ File Number	HQRNORM APPLY 00287868AM22													
RA File Number	03AX04000216 AM22													
Licence No and Date	0311009541/16/12/2021													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Mar/202122/15 dated 17/03/2022 against advance authorization No. 0311002428 dated 11-03-2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>ZINC CITRATE TRIHYDRATE (PURE)</td><td>50000 kg</td><td>1</td><td>CITRIC ACID MONOHYDRATE</td><td>34109.5 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	ZINC CITRATE TRIHYDRATE (PURE)	50000 kg	1	CITRIC ACID MONOHYDRATE	34109.5 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
ZINC CITRATE TRIHYDRATE (PURE)	50000 kg	1	CITRIC ACID MONOHYDRATE	34109.5 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	119 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred

Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00289566AM22
RA File Number	34AX04000036 AM22
Licence No and Date	3411001553/17/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Stoichiometric balance between import and export on molar basis. Complete justification of wastage of raw materials for the manufacturing of export product.	

Case No.	120 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00289569AM22
RA File Number	34AX04000035 AM22
Licence No and Date	3411001554/17/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Stoichiometric balance between import and export on molar basis. Complete justification of wastage of raw materials for the manufacturing of export product.	

Case No.	121 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00288929AM22
RA File Number	03AA040131485 AM22

Licence No and Date	0311009599/17/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Mar/2022122/16 dated 08.04.2022 against advance authorization No. 0311008210 dated 03.11.2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
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.	122 / NC/3/MEET/Oct/202223/11			
Case Status	Case Approved			
Party Name	STERILE INDIA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022			
HQ File Number	HQRNORM APPLY 00288969AM22			
RA File Number	05AX04000134 AM22			
Licence No and Date	0511006992/17/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/May/202223/4 dated 17.06.2022 against advance authorization No. 0510412070 dated 10.10.2019, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Deferoxamine Mesylate Sterile	1 kg	1	Deferoxamine Mesylate USP	1.02 kg

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

Case No.	123 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00291953AM22
RA File Number	05AX04000176 AM22
Licence No and Date	0511007040/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	124 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	INFICHEM PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00291201AM22
RA File Number	52AX04000002 AM22
Licence No and Date	5211001739/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	125 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00291474AM22
RA File Number	08AX04000083 AM22
Licence No and Date	0811003487/20/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	

Copy of COA of import item from foreign supplier showing Potency of Actual Import.

Case No.	126 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00291533AM22
RA File Number	34AX04000052 AM22
Licence No and Date	3411001560/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	127 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00291684AM22
RA File Number	05AX04000180 AM22
Licence No and Date	0511007032/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	128 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SUMAR BIOTECH LLP
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00291905AM22
RA File Number	08AX04000034 AM22
Licence No and Date	0811003488/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	129 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	MELZER CHEMICALS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022

and Date	
HQ File Number	HQRNORM APPLY 00291926AM22
RA File Number	31AA04030064 AM22
Licence No and Date	3111000802/20/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis. Details of indigenous input with quantity.	

Case No.	130 / NC/3/MEET/Oct/202223/11			
Case Status	Case Approved			
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022			
HQ File Number	HQRNORM APPLY 00292436AM22			
RA File Number	03AA040114422 AM22			
Licence No and Date	0311009656/21/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

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

Case No.	131 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00292962AM22
RA File Number	09AA04017854 AM22
Licence No and Date	0911002118/21/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	132 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	NATCO PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00293027AM22
RA File Number	09AX04000043 AM22
Licence No and Date	0911002121/21/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	133 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00293142AM22
RA File Number	05AX04000189 AM22
Licence No and Date	0511007079/21/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	134 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred

Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00293146AM22
RA File Number	34AX04000029 AM22
Licence No and Date	3411001569/21/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	135 / NC/3/MEET/Oct/202223/11													
Case Status	Case Approved													
Party Name	DEEPAK PHENOLICS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022													
HQ File Number	HQRNORM APPLY 00293951AM22													
RA File Number	34AX04000070 AM22													
Licence No and Date	3411001584/22/12/2021													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Aug/202223/6 dated 09.09.2022 against advance authorization No. 3411001756 dated 04.02.2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>Phenol</td><td>7700 MT</td><td>1</td><td>Cumene</td><td>6503.883 MT</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Phenol	7700 MT	1	Cumene	6503.883 MT
Export Product	Qty.	Sl. No.	Import Items	Qty.										
Phenol	7700 MT	1	Cumene	6503.883 MT										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	136 / NC/3/MEET/Oct/202223/11			
Case Status	Case Approved			
Party Name	INDOCO REMEDIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022			
HQ File Number	HQRNORM APPLY 00293646AM22			
RA File Number	03AX04000320 AM22			
Licence No and Date	0311009690/22/12/2021			

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. **0311008055 dated 31.10.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Ketotifen Fumarate ophthalmic solution (5ml Bottle)((Each ml. Contains: Ketotifen (0.025 percentage) Antihistamine) (Equivalent to Ketotifen Fumarate 0.035 percentage) = 1.750 mg per bottle of 5ml) (Net Weight in Export Products is : 700 GRAMS))	1 Number	1	Ketotifen Fumarate	1.785 mg
		2	Bottle	Relevant as per packing policy
		3	Cap	
		4	Dropper	

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

Case No.	137 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00293897AM22
RA File Number	31AX04000017 AM22
Licence No and Date	3111000824/22/12/2021

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. **3111000494 dated 30.07.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export Product	Qty.	Sl. No.	Import Items	Qty.
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ETHYLENEDIAMINE (ORGANIC CHEMICAL)	1 kg	1	MONO ETHANOL AMINE	1.0374 kg
		2	AMMONIA ANHYDROUS	Not allowed, as it is shown indigenous

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

Case No.	138 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00295564AM22
RA File Number	09AX04000038 AM22
Licence No and Date	0911002144/23/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	139 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00295569AM22
RA File Number	09AX04000039 AM22
Licence No and Date	0911002145/23/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	140 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	NEXUS PHARMA CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00296625AM22
RA File Number	08AX04000128 AM22
Licence No and Date	0811003535/24/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09.09.2022** against advance authorization No. **0811003688 dated 06.01.2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Clobetasol Propionate USP	1 kg	1	Betamethasone base	1.00 kg

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

Case No.	141 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	LARK LABORATORIES (INDIA) LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00296972AM22
RA File Number	05AX04000299 AM22
Licence No and Date	0511007234/24/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	142 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00298292AM22
RA File Number	08AX04000091 AM22
Licence No and Date	0811003537/27/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	143 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SRF LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00298304AM22
RA File Number	05AX04000086 AM22
Licence No and Date	0511007243/27/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i Complete technical details as per Annexure to Appendix 4E.	

Case No.	144 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	SAVLA CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00298647AM22
RA File Number	03AX04000385 AM22
Licence No and Date	0311009839/27/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Percentage purity of import item. ii. COA of import item from foreign supplier. iii. Testing Report of import item from Foreign Accredited Institute.	

Case No.	145 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00299344AM22
RA File Number	07AA04038998 AM22
Licence No and Date	0711002737/28/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	

- i. **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. **Stoichiometric balance between import and export on molar basis.**
- iv. **Complete justification of wastage of raw materials for the manufacturing of export product.**

Case No.	146 / NC/3/MEET/Oct/202223/11			
Case Status	Case Approved			
Party Name	MAHARASHTRA ALDEHYDES AND CHEMICALS LTD			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022			
HQ File Number	HQRNORM APPLY 00299560AM22			
RA File Number	03AX04000272 AM22			
Licence No and Date	0311009857/28/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and on the basis of 95% yield, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

Case No.	147 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved
Party Name	MAHARASHTRA ALDEHYDES AND CHEMICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00299562AM22
RA File Number	03AX04000273 AM22
Licence No and Date	0311009858/28/12/2021
Norms Committee Decision:	

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

Export product	Qty.	Sl. No.	Import items	Qty.
TRIETHYL CITRATE	1 kg	1	Anhydrous Citric Acid	0.7322 kg
		2	ETHANOL	0.5263 kg

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

Case No.	148 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00299896AM22
RA File Number	34AX04000090 AM22
Licence No and Date	3411001598/28/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	149 / NC/3/MEET/Oct/202223/11
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00299954AM22
RA File Number	09AX04000070 AM22
Licence No and Date	0911002189/28/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	150 / NC/3/MEET/Oct/202223/11
Case Status	Case Approved

Party Name	GLENFIN CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202223/ 11 and 31/10/2022
HQ File Number	HQRNORM APPLY 00356912AM22
RA File Number	03AX04001153 AM22
Licence No and Date	0311011451/16/02/2022

Norms Committee Decision:

The Committee considered the case as per agenda and as per the clarification given by the firm and taking the yield as 78% (as per application), also 70% recovery of solvent mixture and the price offsetting it with THF, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
1-(4-Hydroxyphenyl)-heptane-1,3-dione	1 kg	1	4-Hydroxyacetophenone	0.79 kg
		2	Tetrahydrofuran	2.30 kg
		3	Ethyl Valerate	0.75 kg
		4	Sodium Tertiary Butoxide	1.65 kg
		5	Acetic Acid	Not allowed, as it is shown indigenous

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