



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

VANIJYA BHAWAN, AKBAR ROAD, CENTRAL DELHI, DELHI, 110011 / वाणिज्य भवन, अकबर

रोड, नई दिल्ली

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III**MEETING No.** NC/3/MEET/Jun/202425/6**DATED:** 01/07/2024Please 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.
- IV. RAs shall ensure compliance of SION, General Notes and Chapter Notes wherever applicable.
- V. RAs shall also ensure that authorization is issued or redeemed based on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less. In this regards, full compliance of provisions of Para 4.12 of FTP, Para 4.16; Para 4.21 and Para 4.51 of HBP shall be made

Meeting No. NC/3/MEET/Jun/202425/6 dated 01/07/2024 of Norms Committee - III for the year 2024-25 was held on 01/07/2024 under the Chairmanship of Shri Rakesh Kumar, Additional 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 2023.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	Shri Rakesh Kumar, Addl. DGFT	DGFT(HQ)

2	Shri Raman Kumar, Deputy DGFT	DGFT(HQ)
3	Shri Dinesh Narain Mathur, Technical Expert (Pharma)	Consultant
4	Shri Shaish Kumar, Technical Expert (Chemical)	Consultant
5	Shri Nand Lal, Technical Expert (Chemical)	Consultant
6	Shri Uttam Dey Sarkar, ASO	DGFT (HQ)

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00001088AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The committee considered the request of the firm for fixation of ad-hoc norms and it has been observed that the purchase orders submitted by the firm were not signed by anyone. Therefore, the Committee has decided to seek clarification from the firm with the following information/documents: 1. Drug Manufacturing Licence (DML) showing approved composition. 2. Master Batch Formula showing net content of all inputs.	

Case No.	2 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00001160AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The committee considered the request of the firm for fixation of ad-hoc norms and it has been observed that the purchase orders submitted by the firm were not signed by anyone, and it is not possible to know whether these purchase orders were formally accepted by both parties. Therefore, the Committee has decided to seek the clarification in this regard from the firm.	

Case No.	3 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024

and Date	
HQ File Number	HQRNORM APPLY 00006267AM23
RA File Number	09AX04000893 AM23
Licence No and Date	0911004453/13/02/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	4 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ANDHRA ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00006448AM23
RA File Number	09AX04001032 AM23
Licence No and Date	0911004503/20/02/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

		7	Acetic Acid	0.89 kg
		8	Potassium Hydroxide Flakes (KOH flakes)	0.185 kg
		9	Methylene Chloride	0.50 kg

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

Case No.	5 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00006487AM23
RA File Number	09AX04001024 AM23
Licence No and Date	0911004510/21/02/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sitagliptin hydrochloride (Pharmaceutical product)	1 kg.	1	Ethyl Trifluoro Acetate	1.71 kg
		2	2,4,5-Tri fluoro phenyl acetic acid	0.86 kg
		3	(R)-Phenyl ethyl amine	0.57 kg
		4	Sodium borohydride	0.16 kg
		5	Acetonitrile	1.14 kg

		6	Methylene dichloride	9.30 kg
		7	Isopropyl alcohol	4.52 kg
		8	Methanol	4.29 kg

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

Case No.	6 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00006770AM23
RA File Number	03AX04005861 AM23
Licence No and Date	0311021934/06/03/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was observed during the Personal Hearing held on 05/03/2024 that they are getting many intermediates manufactured by their supporting manufacturetr and details of for which was not given and the firm also could not explain the confusion raised by the Committee in the yields claim in the process. The Committee has advised to furnish the revised application. However, the same still not received from the firm. Therefore, it was decided that the firm may be again advised to furnish the following documents as sought earlier: 1. Revised Annexure to Appendix-4E 2. Revised Production/Consumption for the last three years certified by CA.	

Case No.	7 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024

HQ File Number	HQRNORM APPLY 00006807AM23																			
RA File Number	09AX04001097 AM23																			
Licence No and Date	0911004646/08/03/2023																			
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> <tr> <td rowspan="4">4-(2-(2-(6,6-dimethylbicyclo [3.1.1] heptan-2-yl)ethoxy)ethyl) morpholine (intermediate)</td><td rowspan="4">1 kg.</td><td>1</td><td>DIHYDRONOPOL</td><td>0.66 kg</td></tr> <tr> <td>2</td><td>TOLUENE</td><td>1.915 kg</td></tr> <tr> <td>3</td><td>SODAMIDE</td><td>0.19 kg</td></tr> <tr> <td>4</td><td>METHANOL</td><td>0.56 kg</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	4-(2-(2-(6,6-dimethylbicyclo [3.1.1] heptan-2-yl)ethoxy)ethyl) morpholine (intermediate)	1 kg.	1	DIHYDRONOPOL	0.66 kg	2	TOLUENE	1.915 kg	3	SODAMIDE	0.19 kg	4	METHANOL	0.56 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
4-(2-(2-(6,6-dimethylbicyclo [3.1.1] heptan-2-yl)ethoxy)ethyl) morpholine (intermediate)	1 kg.	1	DIHYDRONOPOL	0.66 kg																
		2	TOLUENE	1.915 kg																
		3	SODAMIDE	0.19 kg																
		4	METHANOL	0.56 kg																

Case No.	8 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00000093AM24
RA File Number	03AX04000048 AM24
Licence No and Date	0311022711/11/04/2023
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ETHYL ISOBUTYRATE	1 kg.	1	ISOBUTYRIC ACID	0.948 kg

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

Case No.	9 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00000292AM24
RA File Number	03AX04000045 AM24
Licence No and Date	0311022935/19/04/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	10 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00000325AM24
RA File Number	03AX04000169 AM24
Licence No and Date	0311022998/21/04/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	11 / NC/3/MEET/Jun/202425/6			
Case Status	Case Approved			
Party Name	YASHO INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024			
HQ File Number	HQRNORM REVIW00004946AM24			
RA File Number	03AX04000416 AM24			
Licence No and Date	0311023239/01/05/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to revise ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Case No.	12 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00002509AM24
RA File Number	08AX04000510 AM24
Licence No and Date	0811008516/26/06/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Nystatin Cream USP, 100000 units/gm, 15gm (15gm Tube)(Each gram Contains: 100,000 USP Nystatin Units in an aqueous, cream base.	30000 Numbers	1	Nystatin (Nystatin Micronized)	7.37 kg
Nystatin Cream USP, 100000 units/gm, 30gm (30gm Tube) (Each gram Contains: 100,000 USP Nystatin Units in anaqueous, cream base.	620000 Numbers	2	Nystatin (Nystatin Micronized)	304.53 kg

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

Case No.	13 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00002572AM24
RA File Number	08AX04000392 AM24
Licence No and Date	0811008526/26/06/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	
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MOFETIL CAPSULES 250MG (EACH HARD GELATIN CAPSULE CONTAINS: MYCOPHENOLATE MOFETIL PH. EUR. 250MG)			BP / IP / USP / PH. EUR.	
MYCOPHENOLATE MOFETIL TABLETS 500MG(EACH FILM COATED TABLET CONTAINS: MYCOPHENOLATE MOFETIL PH. EUR. 500MG)	1 Number	2	MYCOPHENOLATE MOFETIL EP / BP / IP / USP / PH. EUR.	510.00 mg

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

Case No.	14 / NC/3/MEET/Jun/202425/6				
Case Status	Case Approved				
Party Name	TORRENT PHARMACEUTICALS LTD				
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024				
HQ File Number	HQRNORM APPLY 00002683AM24				
RA File Number	08AX04000542 AM24				
Licence No and Date	0811008532/27/06/2023				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					

(EACH FILM COATED SUSTAINED RELEASE TABLET CONTAINS: INDAPAMIDE PH. EUR. 1.5MG.				
INDAPAMIDE HEMIHYDRATE TABLETS 2.5 MG (INDAPAMIDE HEMIHYDRATE 2.5 MG EQUIVALENT TO INDAPAMIDE 2.44 MG) (EACH FILM COATED TABLET CONTAINS : INDAPAMIDE HEMIHYDRATE PH. EUR. 2.5 MG EQUIVALENT TO INDAPAMIDE 2.44 MG	1 Number	2	INDAPAMIDE EP	2.55 mg / Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	15 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00002734AM24
RA File Number	34AX04000232 AM24
Licence No and Date	3411003838/27/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution, USP 2% & 0.5% - 10 ML(Dorzolamide	1 Number	1	Timolol Maleate USP	69.67 mg

Hydrochloride and Timolol Maleate Ophthalmic Solution, USP 2% & 0.5% - 10 ML.				
Brimonidine Tartrate and Timolol Maleate Ophthalmic solution 0.2% & 0.5% - 5 ML	1 Number	2	Timolol Maleate USP	34.68 mg
Brimonidine Tartrate and Timolol Maleate Ophthalmic solution 0.2% & 0.5% -10 ML	1 Number	3	Timolol Maleate USP	69.36 mg
Brimonidine Tartrate and Timolol Maleate Ophthalmic solution 0.2% & 0.5% - 15 ML	1 Number	4	Timolol Maleate USP	104.04 mg
Timolol Maleate Ophthalmic Gel Forming Solution, 0.5% - 5 ML	1 Number	5	Timolol Maleate USP	34.68 mg
Timolol Maleate Ophthalmic Gel Forming Solution, 0.25% - 5 ML	1 Number	6	Timolol Maleate USP	17.34 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	16 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00002856AM24
RA File Number	03AX04001411 AM24
Licence No and Date	0311024954/28/06/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para	

4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Sl. No	Export Product	Quantity
1	Medical Cream, Ointment, Gel (Mycospor 1% Cream 10 Gm (Tot Wt: 1000Kgs. Net Cont: Bifonazole JP 10 Kgs, Octyldodecanol JP 135 Kgs, Sorbitan Monostearate JP 20 Kgs, Aluminium Tubes 100,000 Nos))	1 Number

S. No	Import Product	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy and General Notes.

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

Case No.	17 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	TERBOL LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00002865AM24
RA File Number	07AX04000446 AM24
Licence No and Date	0711008410/28/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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NIFUROXAZIDE CAPSULES 200MG - "ENTEROCOLIN 200MG"(NIFUROXAZIDE CAPSULES 200MG - "ENTEROCOLIN 200MG" 475500 NOS)	1 Number Capsules	1	NIFUROXAZIDE BP	204 mg/Capsules
RA concerned may take further necessary action as per above decision of NC.				

Case No.	18 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	LINCOLN PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00002874AM24
RA File Number	08AX04000490 AM24
Licence No and Date	0811008569/28/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ALENDRONATE SODIUM TABLETS USP 70 MG (ALENDRONATE SODIUM TABLETS USP 70 MG (PACKING1x4 = 4 NOS IN EACH PACK.)	1 Number	1	SODIUM ALENDRONATE TRIHYDRATE	93.19 mg

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

Case No.	19 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00002880AM24
RA File Number	03AX04001433 AM24
Licence No and Date	0311024964/28/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jan/202324/20 dated 18/01/2024** against advance authorization **No.0311016485 dated 21.07.2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
3-(4-CHLORO-2-FLUORO-5-MERCAPTO-PHENYL)-1-METHYL-6-TRIFLUOROMETHYL-1H-PYRIMIDINE-2,4-DIONE TECHNICAL (PDSH)	1 Kg	1	2 Fluro Aniline	0.66 kg
		2	Ethyl chloroformate	0.55 kg
		3	Ethyl 3 amino -4,4,4 trifluorocrotonate	0.66 kg
		4	Potassium carbonate	0.31 kg
		5	Dimethyl Formamide	Deleted (not given in production/consumption data & also not a main reactant)

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

Case No.	20 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved

Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024													
HQ File Number	HQRNORM APPLY 00003111AM24													
RA File Number	09AX04000258 AM24													
Licence No and Date	0911005298/30/06/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>2-CHLORO-5-METHYLPYRIDINE-4-AMINE</td><td>1 Kg</td><td>1</td><td>2 CHLORO 5 METHYLPYRIDINE</td><td>1.80 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	2-CHLORO-5-METHYLPYRIDINE-4-AMINE	1 Kg	1	2 CHLORO 5 METHYLPYRIDINE	1.80 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
2-CHLORO-5-METHYLPYRIDINE-4-AMINE	1 Kg	1	2 CHLORO 5 METHYLPYRIDINE	1.80 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	21 / NC/3/MEET/Jun/202425/6										
Case Status	Case Approved										
Party Name	BROOKS STERISCIENCE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024										
HQ File Number	HQRNORM APPLY 00003176AM24										
RA File Number	34AX04000101 AM24										
Licence No and Date	3411003857/30/06/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No.0811010864 dated 26.02.2024 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Meropenem for Injection USP</td><td>1 Number</td><td>1</td><td>Sterile Meropenem with</td><td>1.29 gm/1 gm</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Meropenem for Injection USP	1 Number	1	Sterile Meropenem with	1.29 gm/1 gm
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Meropenem for Injection USP	1 Number	1	Sterile Meropenem with	1.29 gm/1 gm							

1000 mg			Sodium Carbonate USP	Injection
Meropenem for Injection USP 500 mg	1 Number	2	Sterile Meropenem with Sodium Carbonate USP	0.645 gm/500 mg Injection

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

Case No.	22 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00003181AM24
RA File Number	08AX04000522 AM24
Licence No and Date	0811008584/30/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No. NC/3/MEET/Mar/202324/26 dated 22/03/2024** against advance authorization **No.0811010864 dated 26.02.2024**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MITOXANTRONE CONCENTRATE FOR SOLUTION FOR INFUSION 2MG/ML, 5ML VIAL	1 Number	1	MITOXANTRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. (Water + Residual Solvent NLT 3.56%)	13.27 mg
MITOXANTRONE CONCENTRATE FOR SOLUTION FOR INFUSION 2MG/ML, 10 ML VIAL	1 Number	2	MITOXANTRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. (Water + Residual Solvent NLT 3.56%)	26.54 mg
MITOXANTRONE	1 Number	3	MITOXANTRONE	38.01 mg

CONCENTRATE FOR SOLUTION FOR INFUSION 2MG/ML, 15 ML VIAL			HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. (Water + Residual Solvent NLT 3.56%)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	23 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00003729AM24
RA File Number	03AX04001457 AM24
Licence No and Date	0311025050/03/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No. NC/3/MEET/Sep/202324/14 dated 27/09/2023** against advance authorization **No.0311026873 dated 04/09/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Agomelatine Citric Acid Co-Crystal	1 Kg	1	(7-METHOXY 1 NAPHTHYL) ACETONITRILE	0.60 kg

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

Case No.	24 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024													
HQ File Number	HQRNORM APPLY 00003730AM24													
RA File Number	03AX04001458 AM24													
Licence No and Date	0311025051/03/07/2023													
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Naftidrofuryl Hydrogen Oxalate</td> <td>1868 Kg</td> <td>1</td> <td>Naftidrofuryl Hydrogen Oxalate Seed</td> <td>18 kg</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Naftidrofuryl Hydrogen Oxalate	1868 Kg	1	Naftidrofuryl Hydrogen Oxalate Seed	18 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Naftidrofuryl Hydrogen Oxalate	1868 Kg	1	Naftidrofuryl Hydrogen Oxalate Seed	18 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	25 / NC/3/MEET/Jun/202425/6													
Case Status	Case Approved													
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024													
HQ File Number	HQRNORM APPLY 00003736AM24													
RA File Number	03AX04001505 AM24													
Licence No and Date	0311025060/03/07/2023													
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Doxorubicin Hydrochloride for Inj. BP 50 MG</td> <td>1 Number</td> <td>1</td> <td>Doxorubicin Hydrochloride IP/BP</td> <td>52.00 mg</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Doxorubicin Hydrochloride for Inj. BP 50 MG	1 Number	1	Doxorubicin Hydrochloride IP/BP	52.00 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Doxorubicin Hydrochloride for Inj. BP 50 MG	1 Number	1	Doxorubicin Hydrochloride IP/BP	52.00 mg										

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

Case No.	26 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00003758AM24
RA File Number	05AX04000871 AM24
Licence No and Date	0511019606/03/07/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DI CYCLO HEXYL PHTHALATE (DCHP) (DI CYCLO HEXYL PHTHALATE (DCHP) (PACKED IN 909 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES	1 Kg	1	PHTHALIC ANHYDRIDE	0.472 kg
		2	CYCLOHEXANOL	0.639 kg
		3	HDPE GRANULES	As per packing policy and General Notes.

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

Case No.	27 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	JUBILANT GENERICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00003937AM24
RA File Number	05AX04000876 AM24

Licence No and Date	0511019620/04/07/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Apr/202425/2 dated 30/04/2024 against advance authorization No.0511019120 dated 01.06.2023 it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Levetiracetam 500 mg tablets	1 Tablet	1	Levetiracetam	510 mg/tablet
Levetiracetam 1000 mg tablets	1 Tablet	2	Levetiracetam	1020 mg/tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	28 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004115AM24
RA File Number	52AX04000093 AM24
Licence No and Date	5211005099/05/07/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- To give justification for low yield of formation of intermediate Semicarbazide HCL from Hydrazine Hydrate 64%. Calculation for the requirement of all the raw materials based on yield of the reaction separately at each stage.	

Case No.	29 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004117AM24
RA File Number	08AX04000578 AM24
Licence No and Date	0811008606/05/07/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 1ML VIAL(EACH ML CONTAINS: VINORELBINE TARTRATE PH.EUR EQ. TO VINORELBINE 10 MG)	1 Vial	1	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR	13.80 mg
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 5ML VIAL(EACH ML CONTAINS: VINORELBINE TARTRATE PH.EUR EQ. TO VINORELBINE 10 MG)	1 Vial	2	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR	69.00 mg

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

Case No.	30 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004222AM24

RA File Number	09AX04000297 AM24
Licence No and Date	0911005327/06/07/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	31 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	BULI CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004235AM24
RA File Number	03AX04001475 AM24
Licence No and Date	0311025181/06/07/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. To indicate the exact percentage of Hexane in export item, because the requirement of raw materials will be different in different concentration. 2. Complete chemical reaction of reactant and product indicating molecular weight of each chemical and yield of the reaction and accordingly calculate the requirement. 3. The commercial value of by-product Lithium Chloride, supported by invoices. 4. Stoichiometric material balance of the reaction. 5. To indicate indigenous items in Annexure to Appendixt-4E.	

Case No.	32 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004244AM24
RA File Number	09AX04000203 AM24
Licence No and Date	0911005339/06/07/2023
Norms Committee Decision:	

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

Exact specification of export product whether 15% or 23 % or 30%

Case No.	33 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004246AM24
RA File Number	34AX04000258 AM24
Licence No and Date	3411003871/06/07/2023

Norms Committee Decision:

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

Copy of Master-Batch formula showing net content of inputs in the export item.

Case No.	34 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	VISWAAT CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004250AM24
RA File Number	03AX04001561 AM24
Licence No and Date	0311025198/06/07/2023

Norms Committee Decision:

The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, 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 weight alongwith stage wise percentage yield on molar basis.
- iii. All technical details as per annexure to appendix 4E for chemical products.
- iv. Stichometric balance between import and export on molar basis.
- v. Details of indigenous input with quantity.

Case No.	35 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004286AM24
RA File Number	09AX04000315 AM24
Licence No and Date	0911005356/07/07/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Phytonadione Injectable Emulsion USP 1 mg/0.5ML	1 Number	1	Phytonadione USP 97% assay	1.134 mg
		2	HYPAK BSCF1MLL W4023 FLUR DAIKYO LID Stoppers	Relevant as per packing policy and General Notes.
		3	HYPAK SCF1MLL 27GA1/2IN-5B P136 RNS4800 Syringe Barrel	Relevant as per packing policy and General Notes.

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

Case No.	36 / NC/3/MEET/Jun/202425/6										
Case Status	Case Approved										
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024										
HQ File Number	HQRNORM APPLY 00004299AM24										
RA File Number	03AX04001599 AM24										
Licence No and Date	0311025255/10/07/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Doxorubicin Hydrochloride for Inj. BP 50 MG</td><td>1 Vial</td><td>1</td><td>Doxorubicin Hydrochloride IP/BP</td><td>55 mg/vial</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Doxorubicin Hydrochloride for Inj. BP 50 MG	1 Vial	1	Doxorubicin Hydrochloride IP/BP	55 mg/vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Doxorubicin Hydrochloride for Inj. BP 50 MG	1 Vial	1	Doxorubicin Hydrochloride IP/BP	55 mg/vial							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	37 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004401AM24
RA File Number	34AX04000275 AM24
Licence No and Date	3411003884/13/07/2023
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	38 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred

Party Name	SOHAN HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004404AM24
RA File Number	31AX04000095 AM24
Licence No and Date	3111002460/13/07/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of DML for Export item. 2. Copy of Master-Batch formula.	

Case No.	39 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004433AM24
RA File Number	03AX04001604 AM24
Licence No and Date	0311025397/14/07/2023
Norms Committee Decision: The committee considered the request of the firm for fixation of ad-hoc norms and it has been observed that the purchase orders submitted by the firm were not signed by anyone, and it is not possible to know whether these purchase orders were formally accepted by both parties. Therefore, the Committee has decided to seek the clarification in this regard from the firm.	

Case No.	40 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004440AM24
RA File Number	03AX04001669 AM24
Licence No and Date	0311025403/14/07/2023
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Dec/202324/19 dated 05/01/2024** against advance authorization **No.0311019551 dated 28/11/2022** it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
OLMESARTAN MEDOXOMIL	1 Kg	1	4-(1-HYDROXY-1-METHYL ETHYL)-2-PROPYL-1H-IMIDAZOLE 5-CARBOXYLIC ACID ETHYL ESTER	0.70 kg
		2	5-(4-BROMOMETHYL) (1,-BROMOMETHYLIPHENYL)-2YL TRIPHENYL-1-H TETRAZOLE; 5-(4-BROMOMETHYL BIPHENYL-2-YL)-1-TRITYL-1H-TET	1.35 kg
		3	4-CHLOROMETHYL-5-METHYL 1,3-DIOXOLEN-2-ONE	0.426 kg
		4	ACETIC ACID GLACIAL	0.60 kg
		5	ACETONE	3.00 kg
		6	METHANOL	2.60 kg
		7	TOLUENE	1.00 kg

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

Case No.	41 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004443AM24
RA File Number	03AX04001084 AM24

Licence No and Date	0311025417/14/07/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	42 / NC/3/MEET/Jun/202425/6													
Case Status	Case Approved													
Party Name	BROOKS STERISCIENCE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024													
HQ File Number	HQRNORM APPLY 00004445AM24													
RA File Number	34AX04000271 AM24													
Licence No and Date	3411003892/14/07/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No.0811010864 dated 26/02/2024 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Meropenem for Injection USP 1000 mg</td><td>1 Number</td><td>1</td><td>Sterile Meropenem with Sodium Carbonate USP</td><td>1.29 gm/1 gm Injection</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Meropenem for Injection USP 1000 mg	1 Number	1	Sterile Meropenem with Sodium Carbonate USP	1.29 gm/1 gm Injection
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Meropenem for Injection USP 1000 mg	1 Number	1	Sterile Meropenem with Sodium Carbonate USP	1.29 gm/1 gm Injection										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	43 / NC/3/MEET/Jun/202425/6			
Case Status	Case Deferred			
Party Name	WEXFORD LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024			
HQ File Number	HQRNORM APPLY 00004448AM24			

RA File Number	07AX04000507 AM24
Licence No and Date	0711008721/14/07/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Export quantity to be given in Numbers in the Advance Authorization.	

Case No.	44 / NC/3/MEET/Jun/202425/6										
Case Status	Case Approved										
Party Name	AMI LIFESCIENCES PVT LTD										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024										
HQ File Number	HQRNORM APPLY 00004482AM24										
RA File Number	34AX04000293 AM24										
Licence No and Date	3411003888/18/07/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Betahistine Dihydrochloride</td><td>1 Kg</td><td>1</td><td>Pyridine 2 Ethanol</td><td>0.852 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Betahistine Dihydrochloride	1 Kg	1	Pyridine 2 Ethanol	0.852 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Betahistine Dihydrochloride	1 Kg	1	Pyridine 2 Ethanol	0.852 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	45 / NC/3/MEET/Jun/202425/6			
Case Status	Case Approved			
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED			
Meeting Number	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024			

and Date											
HQ File Number	HQRNORM APPLY 00004538AM24										
RA File Number	31AX04000105 AM24										
Licence No and Date	3111002491/20/07/2023										
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 95% W/W WHITE GRANULES POWDER</td> <td>1 Kg</td> <td>1</td> <td>DICYANDIAMIDE (DCDA) WHITE POWDER</td> <td>0.530 kg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 95% W/W WHITE GRANULES POWDER	1 Kg	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.530 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 95% W/W WHITE GRANULES POWDER	1 Kg	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.530 kg							

Case No.	46 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ELPPE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004593AM24
RA File Number	03AX04001792 AM24
Licence No and Date	0311025670/24/07/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical reaction of the process, indicating molecular weight of both reactants & products with stage wise and overall yield of the reaction. 2. End use of Export item. 3. Production of the export item vis-à-vis consumption of the raw materials for the last three	

years duly certified by CA.

Case No.	47 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004622AM24
RA File Number	05AX04001146 AM24
Licence No and Date	0511020026/25/07/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Percentage Yield of Reaction.	

Case No.	48 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004626AM24
RA File Number	52AX04000117 AM24
Licence No and Date	5211005254/25/07/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Name of the Bulk drug produced from the export item i.e a drug intermediate. 2. Norms applied for Import item no.1 does not match with the yield given. 3. Requirement and Recovery of Import item no. 2 and no. 3 and their sale value if not recovered with documentary evidence.	

Case No.	49 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004640AM24
RA File Number	03AX04001848 AM24
Licence No and Date	0311025745/25/07/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	50 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004654AM24
RA File Number	08AX04000710 AM24
Licence No and Date	0811008720/26/07/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

(2000 mg/100 mL)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	51 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004659AM24
RA File Number	03AX04001873 AM24
Licence No and Date	0311025786/27/07/2023
Norms Committee Decision:	
The committee considered the request of the firm for fixation of ad-hoc norms and it has been observed that the purchase orders submitted by the firm were not signed by anyone, and it is not possible to know whether these purchase orders were formally accepted by both parties. Therefore, the Committee has decided to seek the clarification in this regard from the firm.	

Case No.	52 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004677AM24
RA File Number	34AX04000343 AM24
Licence No and Date	3411003955/27/07/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Metronidazole Gel Usp 1% 55 gm pump(Metronidazole Gel Usp 1% 55 gm pump	50000 Numbers	1	Metronidazole (Micronized) USP	28.05 kg
Metronidazole Gel Usp 1% 60 gm tube(Metronidazole Gel Usp 1% 60 gm tube	120000 Numbers	2	Metronidazole (Micronized) USP	73.44 kg

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

Case No.	53 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004700AM24
RA File Number	09AX04000394 AM24
Licence No and Date	0911005507/28/07/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	54 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	KELVIN NATURAL MINT PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004732AM24
RA File Number	05AX04001031 AM24
Licence No and Date	0511019800/31/07/2023
Norms Committee Decision:	

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

1. **Percentage composition of Export product.**
2. **COA of import item from foreign supplier.**

Case No.	55 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	NIFTY LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004736AM24
RA File Number	09AX04000399 AM24
Licence No and Date	0911005517/31/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No. NC/3/MEET/Jan/202324/20 dated 18/01/2024** against advance authorization **No.0911003436 dated 03.08.2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
N-[dibenzo [b,f] [1,4] thiazepin -11-YL] piperazine Hydrochloride(BULK DRUG)	1 Kg	1	Thiophenol	0.59 kg
		2	Hydrazien Hydrate 64%	0.688 kg
		3	Poly Phosphoric Acid 117%	4.03 kg

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

Case No.	56 / NC/3/MEET/Jun/202425/6
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Case Status	Case Approved										
Party Name	LECILITE INGREDIENTS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024										
HQ File Number	HQRNORM APPLY 00004750AM24										
RA File Number	50AX04000034 AM24										
Licence No and Date	5011000972/31/07/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No.5011001267 dated 31.01.2024 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>SUNFLOWER LECITHIN POWDER/GRANULES</td><td>1 MT</td><td>1</td><td>SUNFLOWER LECITHIN Liquid (Crude)</td><td>1.40 MT</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	SUNFLOWER LECITHIN POWDER/GRANULES	1 MT	1	SUNFLOWER LECITHIN Liquid (Crude)	1.40 MT
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
SUNFLOWER LECITHIN POWDER/GRANULES	1 MT	1	SUNFLOWER LECITHIN Liquid (Crude)	1.40 MT							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	57 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004751AM24
RA File Number	03AX04001897 AM24
Licence No and Date	0311025909/31/07/2023
Norms Committee Decision: The committee considered the request of the firm for fixation of ad-hoc norms and it has been observed that the purchase orders submitted by the firm were not signed by anyone, and it is not possible to know whether these purchase orders were formally accepted by both parties. Therefore, the Committee has decided to seek the clarification in this regard from the firm.	

Case No.	58 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004779AM24
RA File Number	08AX04000819 AM24
Licence No and Date	0811008977/01/08/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CANDESARTAN CILEXETIL 2 MG TABLETS	1 Number	1	CANDESARTAN CILEXETIL PH.EUR	2.04 mg
CANDESARTAN CILEXETIL 4 MG TABLETS	1 Number	2	CANDESARTAN CILEXETIL PH.EUR	4.08 mg
CANDESARTAN CILEXETIL 8 MG TABLETS	1 Number	3	CANDESARTAN CILEXETIL PH.EUR	8.16 mg
CANDESARTAN CILEXETIL 16 MG TABLETS	1 Number	4	CANDESARTAN CILEXETIL PH.EUR	16.32 mg
CANDESARTAN CILEXETIL 32 MG TABLETS	1 Number	5	CANDESARTAN CILEXETIL PH.EUR	32.64 mg
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 8MG+12.5MG	1 Number	6	CANDESARTAN CILEXETIL PH.EUR	8.16 mg
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 16MG+12.5MG	1 Number	7	CANDESARTAN CILEXETIL PH.EUR	16.32 mg
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32MG+12.5MG	1 Number	8	CANDESARTAN CILEXETIL PH.EUR	32.64 mg

CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32MG+25MG	1 Number	9	CANDESARTAN CILEXETIL PH.EUR	32.64 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	59 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004788AM24
RA File Number	07AX04000660 AM24
Licence No and Date	0711008872/02/08/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Rebamipide 100mg Tablets	1 Number Tablet	1	Rebamipide JP	102.00 mg
		2	Ethyl Alcohol 200 Proof	0.19 ml

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

Case No.	60 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004796AM24

RA File Number	34AX04000209 AM24
Licence No and Date	3411003978/02/08/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	61 / NC/3/MEET/Jun/202425/6																
Case Status	Case Approved																
Party Name	BEST VALUE CHEM PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024																
HQ File Number	HQRNORM APPLY 00004798AM24																
RA File Number	34AX04000210 AM24																
Licence No and Date	3411003980/02/08/2023																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Dec/202324/17 dated 20/12/2023 against advance authorization No.3411002472 dated 01/07/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="3">MELONAL (2,6-dimethylhept-5-enal) (Clear colorless liquid)</td><td rowspan="3">1 Kg</td><td>1</td><td>Methyl Heptenone</td><td>1.50 kg</td></tr><tr><td>2</td><td>Methyl Mono Chloro Acetate</td><td>1.72 kg</td></tr><tr><td>3</td><td>Sodium Methoxide</td><td>0.8711 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MELONAL (2,6-dimethylhept-5-enal) (Clear colorless liquid)	1 Kg	1	Methyl Heptenone	1.50 kg	2	Methyl Mono Chloro Acetate	1.72 kg	3	Sodium Methoxide	0.8711 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
MELONAL (2,6-dimethylhept-5-enal) (Clear colorless liquid)	1 Kg	1	Methyl Heptenone	1.50 kg													
		2	Methyl Mono Chloro Acetate	1.72 kg													
		3	Sodium Methoxide	0.8711 kg													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	62 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	DEV BHOOMI ENTERPRISES
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004815AM24
RA File Number	05AX04001219 AM24
Licence No and Date	0511020221/03/08/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Percentage composition of Export product. 2. COA of import item from foreign supplier.	

Case No.	63 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	VINCIT LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004827AM24
RA File Number	05AX04001062 AM24
Licence No and Date	0511020229/03/08/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Complete chemical reactions with molecular weight alongwith stage wise percentage yield on molar basis.	

Case No.	64 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004860AM24
RA File Number	03AX04001676 AM24
Licence No and Date	0311026031/04/08/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- I. Copy of DML for Export item. II. Copy of Master-Batch formula.	

Case No.	65 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004867AM24
RA File Number	09AX04000370 AM24
Licence No and Date	0911005577/04/08/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of DML for Export item. 2. Copy of Master-Batch Formula. 3. Technical justification of 23% wastage claimed in 4E. 4. Documented description of import item and description given in Bill of entry.	

Case No.	66 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024

HQ File Number	HQRNORM APPLY 00004930AM24
RA File Number	09AX04000371 AM24
Licence No and Date	0911005594/08/08/2023
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant documents.	

Case No.	67 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	S KANT HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004943AM24
RA File Number	03AX04002077 AM24
Licence No and Date	0311026147/09/08/2023
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	68 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004944AM24
RA File Number	07AX04000704 AM24
Licence No and Date	0711008930/09/08/2023
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	69 / NC/3/MEET/Jun/202425/6
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Case Status	Case Approved
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004949AM24
RA File Number	08AX04000854 AM24
Licence No and Date	0811009060/09/08/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202324/26 dated 22/03/2024** against advance authorization **No.0811010864 dated 26/02/2024**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MEROPENEM FOR INJECTION 500MG (Meropenem 500mg Powder for Solution for Injection or Infusion.Each vial contains Active Pharmaceutical Ingredients Meropenem Trihydrate Eqv. to Meropenem Anhydrous 500mg Excipients: Anhydrous Sodium Carbonate 104mg, Equivalent to 45.1mg of Sodium)	1 Number	1	STERILE MIXTURE OF MEROPENEM AND SODIUM CARBONATE	0.645 gm/500 mg Injection
MEROPENEM FOR INJECTION 1gm (Meropenem 1.0 GM Powder for Solution for Injection or Infusion. Each vial contains Active Pharmaceutical Ingredients Meropenem Trihydrate Eqv.to Meropenem Anhydrous 1000 mg Excipients: Anhydrous Sodium Carbonate 208mg, Equivalent to 90.2mg of Sodium)	1 Number	2	STERILE MIXTURE OF MEROPENEM AND SODIUM CARBONATE	1.29 gm/1 gm Injection

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

Case No.	70 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004957AM24
RA File Number	03AX04002106 AM24
Licence No and Date	0311026174/09/08/2023
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee with sampel of export and import items such as import item (i) BOP Infusion, (ii) BOP Injection, (iii) SSC Infusion and (iv) SSC Injection.	

Case No.	71 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004971AM24
RA File Number	03AX04002029 AM24
Licence No and Date	0311026195/10/08/2023
Norms Committee Decision: The committee considered the request of the firm for fixation of ad-hoc norms and it has been observed that the purchase orders submitted by the firm were not signed by anyone, and it is not possible to know whether these purchase orders were formally accepted by both parties. Therefore, the Committee has decided to seek the clarification in this regard from the firm.	

Case No.	72 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004972AM24
RA File Number	03AX04002023 AM24

Licence No and Date	0311026196/10/08/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	73 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	BULI CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004985AM24
RA File Number	03AX04002061 AM24
Licence No and Date	0311026225/10/08/2023
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. To indicate the exact percentage of Hexane in export item, because the requirement of raw materials will be different in different concentration. 2. Complete chemical reaction of reactant and product indicating molecular weight of each chemical and yield of the reaction and accordingly calculate the requirement. 3. The commercial value of by-product Lithium Chloride, supported by invoices. 4. Stoichiometric material balance of the reaction. 5. To indicate indigenous items in Annexure to Appendix-4E.	

Case No.	74 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	BROOKS STERISCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00004995AM24
RA File Number	34AX04000179 AM24
Licence No and Date	3411004010/10/08/2023
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202324/26 dated 22/03/2024** against advance authorization **No.0811010864 dated 26/02/2024**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Meropenem for Injection USP 1000 mg	1 Number	2	Meropenem with Sodium Carbonate USP	1.29 gm/1 gm Injection

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

Case No.	75 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ENCEE AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005011AM24
RA File Number	32AX04000274 AM24
Licence No and Date	3211005388/11/08/2023

Norms Committee Decision:

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

- 1. Stoichiometric balance in the chemical reaction given at step 4 is not correct.**
- 2. Commercial value of by-products formed in the manufacturing process.**
- 3. Calculation for the requirement of the imported raw material based on yield with justification of asking high quantity of raw material Glycerine.**

Case No.	76 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005073AM24
RA File Number	08AX04000916 AM24
Licence No and Date	0811009102/16/08/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202324/26 dated 22/03/2024** against advance authorization **No.0811010469 dated 09/01/2024**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Opipramol Dihydrochloride Tablets 50 MG (OPIPRAMOL HEUMANN 50 MG) (Each film coated tablet contains: Opipramol Dihydrochloride 50 mg Excipients. q.s.Colors: Titanium DioxideandYellow OxideofIron.	1 Number	1	Opipramol Dihydrochloride	51 mg/Tablet
Opipramol Dihydrochloride Tablets 100 MG (OPIPRAMOL HEUMANN 100 MG) (Each film coated tablet contains: Opipramol Dihydrochloride 100 mg Excipients. q.s. Colors: Titanium Dioxide and Yellow Oxide of Iron. Net content of active ingredient Opipramol Dihydrochloride should not be less than 235.000 kgs in export product.)	1 Number	2	Opipramol Dihydrochloride	102 mg/Tablet

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

Case No.	77 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred

Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005075AM24
RA File Number	08AX04000894 AM24
Licence No and Date	0811009108/16/08/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	78 / NC/3/MEET/Jun/202425/6			
Case Status	Case Approved			
Party Name	PIL PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024			
HQ File Number	HQRNORM APPLY 00005085AM24			
RA File Number	05AX04001384 AM24			
Licence No and Date	0511020419/16/08/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

AMOXICLAV ORAL SUSPENSION BP 312.5 MG/5ML, AMOXYCILLIN AND POTASSIUM CLAVULANATE BP 250/62.5MG)			BP/USP Plain	
MOXIPIIL CV 457 (100 ML)(CO-AMOXICLAV ORAL SUSPENSION BP 457 MG/5ML, AMOXYCILLIN AND POTASSIUM CLAVULANATE BP 400/57MG)	1 Number	4	Amoxycillin Trihydrate BP/USP Plain	8400.0 mg
MOXIPIIL125 (100 ML)(AMOXICILLIN FOR ORAL SUSPENSION USP 125 MG/5ML)	1 Number	5	Amoxycillin Trihydrate BP/USP Plain	2625.0 mg
MIXCLAV DS (60ML)(CO-AMOXICLAV 250 MG/62.5MG PER 5ML POWDER FOR SUSPENSION, AMOXYCILLIN AND POTASSIUM CLAVULANATE BP 250/62.5MG)	1 Number	6	Amoxycillin Trihydrate BP/USP Plain	3150.0 mg
FAXICLAV DS (60ML)(CO-AMOXICLAV 250 MG/62.5MG PER 5ML POWDER FOR SUSPENSION, AMOXYCILLIN AND POTASSIUM CLAVULANATE BP 250/62.5MG)	1 Number	7	Amoxycillin Trihydrate BP/USP Plain	3150.0 mg
MOXIPIIL 250 (100 ML)(AMOXICILLIN FOR ORAL SUSPENSION USP 250 MG/5ML)	1 Number	8	Amoxycillin Trihydrate BP/USP Plain	5250.0 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	79 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ADCOCK INGRAM LIMITED
Meeting Number	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024

and Date														
HQ File Number	HQRNORM APPLY 00005087AM24													
RA File Number	07AX04000732 AM24													
Licence No and Date	0711008971/16/08/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/May/202425/4 dated 06/06/2024 against advance authorization No.0711007675 dated 29/05/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">FERROUS FORTE TABLETS (Vitamin C (as Ascorbic Acid) -71mg (248.500 KGS) +Iron (From Ferrous Bisglycinate Chelate- 126mg (441.000 KGS) With Other Essential Vitamins & Minerals (No of Tabs-3500000))</td><td rowspan="2">1 Number</td><td>1</td><td>ASCORBIC ACID DC 97 Percentage SF. I.H</td><td>63.087 mg</td></tr><tr><td>2</td><td>IRON BISGLYCINATE</td><td>122.400 mg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	FERROUS FORTE TABLETS (Vitamin C (as Ascorbic Acid) -71mg (248.500 KGS) +Iron (From Ferrous Bisglycinate Chelate- 126mg (441.000 KGS) With Other Essential Vitamins & Minerals (No of Tabs-3500000))	1 Number	1	ASCORBIC ACID DC 97 Percentage SF. I.H	63.087 mg	2	IRON BISGLYCINATE	122.400 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
FERROUS FORTE TABLETS (Vitamin C (as Ascorbic Acid) -71mg (248.500 KGS) +Iron (From Ferrous Bisglycinate Chelate- 126mg (441.000 KGS) With Other Essential Vitamins & Minerals (No of Tabs-3500000))	1 Number	1	ASCORBIC ACID DC 97 Percentage SF. I.H	63.087 mg										
		2	IRON BISGLYCINATE	122.400 mg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	80 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005088AM24
RA File Number	09AX04000448 AM24
Licence No and Date	0911005633/16/08/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No.0911006637 dated 24/01/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CARBIDOPA 12.5MG LEVODOPA 50MG TABLETS	1 Number	1	CARBIDOPA	12.75 mg
		2	LEVODOPA	51.00 mg

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

Case No.	81 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005109AM24
RA File Number	03AX04001779 AM24
Licence No and Date	0311025949/18/08/2023
Norms Committee Decision: The committee considered the request of the firm for fixation of ad-hoc norms and it has been observed that the purchase orders submitted by the firm were not signed by anyone, and it is not possible to know whether these purchase orders were formally accepted by both parties. Therefore, the Committee has decided to seek the clarification in this regard from the firm.	

Case No.	82 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005137AM24
RA File Number	52AX04000128 AM24
Licence No and Date	5211005508/21/08/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the	

TE, it was decided to call for following information/documents from the firm:-

1. **Name of the Bulk drug produced from the export item i.e a drug intermediate.**
2. **Norms applied for Import item no.1 does not match with the yield given.**
3. **Requirement and Recovery of Import item no. 2 and no. 3 and their sale value if not recovered with documentary evidence.**

Case No.	83 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005146AM24
RA File Number	08AX04000944 AM24
Licence No and Date	0811009157/21/08/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Apr/202425/2 dated 30/04/2024** against advance authorization **No.0811008434 dated 16/06/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)	1 Number	1	Tranexamic acid	1.05 gm/100 ml Vial

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

Case No.	84 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024																		
HQ File Number	HQRNORM APPLY 00005152AM24																		
RA File Number	05AX04001449 AM24																		
Licence No and Date	0511020498/21/08/2023																		
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Apr/202324/1 dated 28/04/2023 against advance authorization No.0511016259 dated 08/12/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>ACETAZOLAMIDE TABLETS USP 125 MG</td> <td>1 Number</td> <td>1</td> <td>ACETAZOLAMIDE USP</td> <td>127.50 mg</td> </tr> <tr> <td>ACETAZOLAMIDE TABLETS USP 250 MG</td> <td>1 Number</td> <td>2</td> <td>ACETAZOLAMIDE USP</td> <td>255.00 mg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ACETAZOLAMIDE TABLETS USP 125 MG	1 Number	1	ACETAZOLAMIDE USP	127.50 mg	ACETAZOLAMIDE TABLETS USP 250 MG	1 Number	2	ACETAZOLAMIDE USP	255.00 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
ACETAZOLAMIDE TABLETS USP 125 MG	1 Number	1	ACETAZOLAMIDE USP	127.50 mg															
ACETAZOLAMIDE TABLETS USP 250 MG	1 Number	2	ACETAZOLAMIDE USP	255.00 mg															

Case No.	85 / NC/3/MEET/Jun/202425/6								
Case Status	Case Approved								
Party Name	MANKIND PHARMA LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024								
HQ File Number	HQRNORM APPLY 00005153AM24								
RA File Number	05AX04001447 AM24								
Licence No and Date	0511020506/21/08/2023								
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					

Fenofibrate Tablets USP, 54 mg	20000000 Tablets	1	FENOFIBRATE USP	1101.6 kg
Fenofibrate Tablets USP, 160 mg	10128000 Tablets	2	FENOFIBRATE USP	1652.89 kg

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

Case No.	86 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005154AM24
RA File Number	05AX04001448 AM24
Licence No and Date	0511020507/21/08/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of DML for Export item. 2. Copy of Master-Batch formula.	

Case No.	87 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	SHARP MINT LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005169AM24
RA File Number	05AX04001349 AM24
Licence No and Date	0511020338/22/08/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the	

TE, 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 weight alongwith stage wise percentage yield on molar basis.
- iii. All technical details as per annexure to appendix 4E for chemical products.
- iv. Stichometric balance between import and export on molar basis.
- v. Details of indigenous input with quantity.

Case No.	88 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005202AM24
RA File Number	34AX04000404 AM24
Licence No and Date	3411004043/23/08/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	89 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	SPAR PHARMA LLP
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005203AM24
RA File Number	09AX04000344 AM24
Licence No and Date	0911005672/23/08/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202324/1 dated 28/04/2023 against advance authorization No.0511016259 dated 08/12/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-FLUORO-a-2-METHYL-1-OXOPROPYL)-g- OXO-N-B-DIPHENYL BENZENE BUTANEAMIDE (DIKETONE, INTERMEDIATE FOR ATORVASTATIN / DKT- 3(SOLID)	1 Kg	1	ANILINE OIL	0.47 kg
		2	FLUOROBENZENE	0.52 kg
		3	ACETONE	0.50 kg

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

Case No.	90 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005258AM24
RA File Number	03AX04002280 AM24
Licence No and Date	0311026646/28/08/2023
Norms Committee Decision: The committee considered the request of the firm for fixation of ad-hoc norms and it has been observed that the purchase orders submitted by the firm were not signed by anyone, and it is not possible to know whether these purchase orders were formally accepted by both parties. Therefore, the Committee has decided to seek the clarification in this regard from the firm.	

Case No.	91 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005263AM24

RA File Number	08AX04001023 AM24
Licence No and Date	0811009216/28/08/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	92 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005281AM24
RA File Number	08AX04000923 AM24
Licence No and Date	0811009151/29/08/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	93 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	DEV BHOOMI ENTERPRISES
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005292AM24
RA File Number	05AX04001460 AM24
Licence No and Date	0511020678/29/08/2023
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Percentage composition of Export product. 2. COA of import item from foreign supplier.	

Case No.	94 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	PARAGON FINE AND SPECIALITY CHEMICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005306AM24
RA File Number	08AX04000985 AM24
Licence No and Date	0811009232/29/08/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete chemical reactions with molecular and structural formula and molecular weight alongwith stage wise percentage yield on molar basis.	

Case No.	95 / NC/3/MEET/Jun/202425/6										
Case Status	Case Approved										
Party Name	EMCURE PHARMACEUTICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024										
HQ File Number	HQRNORM APPLY 00005336AM24										
RA File Number	31AX04000151 AM24										
Licence No and Date	3111002604/31/08/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Benazepril Hydrochloride Tablets USP 5 mg(EACH FILM COATED TABLET CONTAIN : Benazepril Hydrochloride USP 5 MG</td><td>1 Number</td><td>1</td><td>BENAZEPRIL HYDROCHLORIDE USP</td><td>5.10 mg/Tablet</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Benazepril Hydrochloride Tablets USP 5 mg(EACH FILM COATED TABLET CONTAIN : Benazepril Hydrochloride USP 5 MG	1 Number	1	BENAZEPRIL HYDROCHLORIDE USP	5.10 mg/Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Benazepril Hydrochloride Tablets USP 5 mg(EACH FILM COATED TABLET CONTAIN : Benazepril Hydrochloride USP 5 MG	1 Number	1	BENAZEPRIL HYDROCHLORIDE USP	5.10 mg/Tablet							

Benazepril Hydrochloride Tablets USP 5 mg(EACH FILM COATED TABLET CONTAIN : Benazepril Hydrochloride USP 5 MG	1 Number	2	BENAZEPRIL HYDROCHLORIDE USP	5.10 mg/Tablet
Benazepril Hydrochloride Tablets USP 10 mg(EACH FILM COATED TABLET CONTAIN : Benazepril Hydrochloride USP 10 MG	1 Number	3	BENAZEPRIL HYDROCHLORIDE USP	10.20 mg/Tablet
Benazepril Hydrochloride Tablets USP 10 mg(EACH FILM COATED TABLET CONTAIN : Benazepril Hydrochloride USP 10 MG	1 Number	4	BENAZEPRIL HYDROCHLORIDE USP	10.20 mg/Tablet
Benazepril Hydrochloride Tablets USP 20 mg(EACH FILM COATED TABLET CONTAIN : Benazepril Hydrochloride USP 20 MG	1 Number	5	BENAZEPRIL HYDROCHLORIDE USP	20.40 mg/Tablet
Benazepril Hydrochloride Tablets USP 20 mg(EACH FILM COATED TABLET CONTAIN : Benazepril Hydrochloride USP 20 MG	1 Number	6	BENAZEPRIL HYDROCHLORIDE USP	20.40 mg/Tablet
Benazepril Hydrochloride Tablets USP 40 mg(EACH FILM COATED TABLET CONTAIN : Benazepril Hydrochloride USP 40 MG	1 Number	7	BENAZEPRIL HYDROCHLORIDE USP	40.80 mg/Tablet
Benazepril Hydrochloride Tablets USP 40 mg(EACH FILM COATED TABLET CONTAIN : Benazepril Hydrochloride USP 40 MG	1 Number	8	BENAZEPRIL HYDROCHLORIDE USP	40.80 mg/Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	96 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	MANNITAB PHARMA SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005338AM24
RA File Number	31AX04000075 AM24
Licence No and Date	3111002606/31/08/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	97 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	CHEMPLAST SANMAR LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005348AM24
RA File Number	04AX04000283 AM24
Licence No and Date	0411005945/31/08/2023
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Commercial value of by-products formed in the manufacturing export item with providing sales invoice. 2. Stage wise and overall yield of the reaction with calculation of requirement of imported raw materials. 3. Current production/consumption data duly certified by CA.	

Case No.	98 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	INNOVARE LABS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005353AM24
RA File Number	26AX04000049 AM24
Licence No and Date	2611001116/31/08/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Reason for not giving chemical name of export item in application and to indicate its end use. 2. Full form of WOAHH and do not use abbreviations in technical details. 3. Highlight the imported items in chemical reaction and to indicate separately whether it is used as raw material, catalyst, solvent, purifier etc., as the case may be. 4. Justification for low yield at each stage, giving overall yield of the reaction. 5. The commercial value of by-product formed in the process.	

Case No.	99 / NC/3/MEET/Jun/202425/6										
Case Status	Case Approved										
Party Name	NEOGEN CHEMICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024										
HQ File Number	HQRNORM APPLY 00005389AM24										
RA File Number	03AX04002443 AM24										
Licence No and Date	0311026825/01/09/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>ETHYL ISOBUTYRATE</td><td>1 kg.</td><td>1</td><td>ISOBUTYRIC ACID</td><td>0.948 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ETHYL ISOBUTYRATE	1 kg.	1	ISOBUTYRIC ACID	0.948 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
ETHYL ISOBUTYRATE	1 kg.	1	ISOBUTYRIC ACID	0.948 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	100 / NC/3/MEET/Jun/202425/6			
Case Status	Case Approved			
Party Name	FARBE FIRMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024			
HQ File Number	HQRNORM APPLY 00005427AM24			
RA File Number	34AX04000424 AM24			
Licence No and Date	3411004082/04/09/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Case No.	101 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	STANEX DRUGS AND CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005456AM24
RA File Number	09AX04000507 AM24
Licence No and Date	0911005765/05/09/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	102 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005462AM24
RA File Number	08AX04001060 AM24
Licence No and Date	0811009279/05/09/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- I. Copy of DML for Export item.	

Case No.	103 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005504AM24
RA File Number	34AX04000414 AM24
Licence No and Date	3411004086/08/09/2023
Norms Committee Decision: The case is under consideration and TE was requested to expedite their comments.	

Case No.	104 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024

HQ File Number	HQRNORM APPLY 00005505AM24															
RA File Number	34AX04000427 AM24															
Licence No and Date	3411004087/08/09/2023															
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> <tr> <td>Clindamycin Phosphate Gel USP 1 % - 30 gm tube(Clindamycin Phosphate Gel USP 1 % - 30 gm tube</td><td>1 Number</td><td>1</td><td>Clindamycin Phosphate USP</td><td>0.306 gm/Tube</td></tr> <tr> <td>Clindamycin Phosphate Gel USP 1 % - 60 gm tube(Clindamycin Phosphate Gel USP 1 % - 60 gm tube</td><td>1 Number</td><td>2</td><td>Clindamycin Phosphate USP</td><td>0.612 gm/Tube</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Clindamycin Phosphate Gel USP 1 % - 30 gm tube(Clindamycin Phosphate Gel USP 1 % - 30 gm tube	1 Number	1	Clindamycin Phosphate USP	0.306 gm/Tube	Clindamycin Phosphate Gel USP 1 % - 60 gm tube(Clindamycin Phosphate Gel USP 1 % - 60 gm tube	1 Number	2	Clindamycin Phosphate USP	0.612 gm/Tube
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Clindamycin Phosphate Gel USP 1 % - 30 gm tube(Clindamycin Phosphate Gel USP 1 % - 30 gm tube	1 Number	1	Clindamycin Phosphate USP	0.306 gm/Tube												
Clindamycin Phosphate Gel USP 1 % - 60 gm tube(Clindamycin Phosphate Gel USP 1 % - 60 gm tube	1 Number	2	Clindamycin Phosphate USP	0.612 gm/Tube												

Case No.	105 / NC/3/MEET/Jun/202425/6					
Case Status	Case Approved					
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024					
HQ File Number	HQRNORM APPLY 00005523AM24					
RA File Number	03AX04002548 AM24					
Licence No and Date	0311026958/08/09/2023					
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.		

Fluorouracil INJ BP 500 MG/10 ML	1 Vial	1	Fluorouracil IP/BP	538 mg/vial
Fluorouracil INJ BP 1000 MG/20 ML	1 Vial	2	Fluorouracil IP/BP	1050 mg/vial

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

Case No.	106 / NC/3/MEET/Jun/202425/6													
Case Status	Case Approved													
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024													
HQ File Number	HQRNORM APPLY 00005529AM24													
RA File Number	03AX04002585 AM24													
Licence No and Date	0311026961/08/09/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No.0311024825 dated 23/06/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Chloroquine Phosphate (CQP)</td><td>1 Kg</td><td>1</td><td>NOVALDIAMINE</td><td>0.411 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Chloroquine Phosphate (CQP)	1 Kg	1	NOVALDIAMINE	0.411 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Chloroquine Phosphate (CQP)	1 Kg	1	NOVALDIAMINE	0.411 kg										
RA concerned may take further necessary action as per above decision of NC														

Case No.	107 / NC/3/MEET/Jun/202425/6			
Case Status	Case Deferred			
Party Name	DEV BHOOMI ENTERPRISES			
Meeting Number	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024			

and Date	
HQ File Number	HQRNORM APPLY 00005544AM24
RA File Number	05AX04001629 AM24
Licence No and Date	0511020833/11/09/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Percentage composition of Export product. 2. COA of import item from foreign supplier.	

Case No.	108 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005546AM24
RA File Number	03AX04002544 AM24
Licence No and Date	0311026992/11/09/2023
Norms Committee Decision: The committee considered the request of the firm for fixation of ad-hoc norms and it has been observed that the purchase orders submitted by the firm were not signed by anyone, and it is not possible to know whether these purchase orders were formally accepted by both parties. Therefore, the Committee has decided to seek the clarification in this regard from the firm.	

Case No.	109 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ALCHEMIE FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005547AM24
RA File Number	03AX04002513 AM24
Licence No and Date	0311026994/11/09/2023
Norms Committee Decision:	

The case is under consideration and TE was requested to expedite his comments.

Case No.	110 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	MAXMED LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005549AM24
RA File Number	05AX04001595 AM24
Licence No and Date	0511020841/11/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Amoxicillin and Potassium Clavulanate 625MG Tablet ((Each Tablet contains Amoxicillin 500mg &Potassium Clavulanate equivalent to Clavunic Acid 125mg))	1 Number	1	Amoxicillin Trihydrate 500mg	580.94 mg
		2	DILUTED CLAVULANATE (1:1)	303.773 mg
Amoxicillin Capsule 500mg ((Each Capsule Contains Amoxicillin 500mg))	1 Number	3	AMOXICILLIN TRIHYDRATE 500mg	580.94 mg
Amoxicillin Tablet 500mg ((Each Tablet Contains Amoxicillin 500mg))	1Number	4	AMOXICILLIN TRIHYDRATE 500mg	575.00 mg

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

Case No.	111 / NC/3/MEET/Jun/202425/6
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Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005581AM24
RA File Number	09AX04000504 AM24
Licence No and Date	0911005783/11/09/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	112 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005583AM24
RA File Number	09AX04000512 AM24
Licence No and Date	0911005784/11/09/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	113 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005607AM24
RA File Number	34AX04000462 AM24
Licence No and Date	3411004113/12/09/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/May/202425/4 dated 06/06/2024 against advance authorization No.3411003766 dated 31/05/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Fluorouracil Injection USP 2.5 gm 50 ML	1 Number	1	Fluorouracil USP	2.60 gm
Fluorouracil Injection USP 5 gm 100 ML	1 Number	2	Fluorouracil USP	5.20 gm

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

Case No.	114 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005618AM24
RA File Number	03AX04002659 AM24
Licence No and Date	0311027072/13/09/2023

Norms Committee Decision:

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Clobetasol Propionate Foam 0.05percent 50gm((Net. wt. of Net. wt. of Clobetasol Propionate USP (Micronized) is 1.00 Kgs.))	40000 Number	1	Clobetasol Propionate USP (Micronized)	19.93 kg
2	Clobetasol Propionate Foam 0.05percent 100gm((Net. wt. of Clobetasol Propionate USP (Micronized) is 2.00 Kgs.))	40000 Number			
3	Clobetasol Propionate Cream USP 0.05percent (Pack Size 15gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.300 Kgs))	40000 Number			

4	Clobetasol Propionate Cream USP 0.05percent (Pack size 30gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.600 Kgs))	40000 Number			
5	Clobetasol Propionate Cream USP 0.05percent (Pack size 45 gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.900 Kgs))	40000 Number			
6	Clobetasol Propionate Cream USP 0.05percent (Pack size 60gm)((Net Weight of Clobetasol Propionate USP (Micronized) 1.200 Kgs))	40000 Number			
7	Clobetasol Propionate Ointment USP 0.05percent (Pack size 15gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.300 Kgs))	40000 Number			
8	Clobetasol Propionate Ointment USP 0.05percent (Pack size 30gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.600 Kgs))	40000 Number			
9	Clobetasol Propionate Ointment USP 0.05percent (Pack size 45gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.900 Kgs))	40000 Number			
10	Clobetasol Propionate Ointment USP 0.05percent (Pack size 60gm)((Net Weight of Clobetasol Propionate USP (Micronized) 1.200 Kgs))	40000 Number			
11	Clobetasol Propionate Spray 0.05percent (Pack size 59ml)((Net Weight of Clobetasol Propionate USP (Micronized) 1.180 Kgs))	40000 Number			
12	Clobetasol Propionate Spray 0.05percent (Pack size 125ml)((Net Weight of Clobetasol Propionate USP (Micronized) 2.500 Kgs))	40000 Number			
13	Clobetasol Prop. Top Sol USP, 0.05percent 25ml((Net Weight of Clobetasol Propionate USP (Micronized) 0.500 Kgs))	40000 Number			
14	Clobetasol Prop. Top Sol USP, 0.05percent 50ml((Net Weight of Clobetasol Propionate USP (Micronized) 1.000 Kgs))	40000 Number			
15	Clobetasol Pro Shampoo, 0.05 percent 118ml((Net	40000			

	Weight of Clobetasol Propionate USP (Micronized) 2.360 Kgs))	Number			
16	Clobetasol Propionate Foam 0.05percent 100gm (Emulsion Formulation)((Net. wt. of Clobetasol Propionate USP (Micronized) is 2.000 Kgs.))	40000 Number			
17	Clobetasol Propionate Foam 0.05percent 50gm (Emulsion Formulation)((Net. wt. of Clobetasol Propionate USP (Micronized) is 1.000 Kgs.))	40000 Number			

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

Case No.	115 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	DELTA FINOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005619AM24
RA File Number	03AX04002566 AM24
Licence No and Date	0311027073/13/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2-Bromo-4,5-dimethoxy benzyl bromide	1 kg.	1	Veratraldehyde	0.596 kg.
		2	Sodium borohydride	0.06 kg.
		3	Liquid Bromine	0.69 kg.
		4	Chloroform	2.1 kg.

		5	Methyl Tert. Butyl Ether	0.84 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	116 / NC/3/MEET/Jun/202425/6													
Case Status	Case Approved													
Party Name	STERLING SPECIALITY CHEMICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024													
HQ File Number	HQRNORM APPLY 00005632AM24													
RA File Number	03AX04002593 AM24													
Licence No and Date	0311027082/13/09/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>2-Ethylhexyl Thioglycolate (EHTG)</td><td>1 Kg</td><td>1</td><td>2-ETHYL HEXANOL</td><td>0.684 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	2-Ethylhexyl Thioglycolate (EHTG)	1 Kg	1	2-ETHYL HEXANOL	0.684 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
2-Ethylhexyl Thioglycolate (EHTG)	1 Kg	1	2-ETHYL HEXANOL	0.684 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	117 / NC/3/MEET/Jun/202425/6			
Case Status	Case Approved			
Party Name	MAXMED LIFE SCIENCES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024			
HQ File Number	HQRNORM APPLY 00005644AM24			

RA File Number	05AX04001722 AM24			
Licence No and Date	0511020940/13/09/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Amoxicillin and Potassium Clavulanate 625MG Tablet((Each Tablet contains Amoxicillin 500mg &Potassium Clavulanate equivalent to Clavunic Acid 125mg))	1 Number	1	Amoxicillin Trihydrate 500mg	580.94 mg
		2	DILUTED CLAVULANATE (1:1)	303.773 mg
Amoxicillin Capsule 500mg((Each Capsule Contains Amoxicillin 500mg))	1 Number	3	AMOXICILLIN TRIHYDRATE 500mg	580.94 mg
Amoxicillin Tablet 500mg((Each Tablet Contains Amoxicillin 500mg))	1Number	4	AMOXICILLIN TRIHYDRATE 500mg	575.00 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	118 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005691AM24
RA File Number	03AX04002669 AM24
Licence No and Date	0311027142/14/09/2023
Norms Committee Decision:	
The committee considered the request of the firm for fixation of ad-hoc norms and it has been observed that the purchase orders submitted by the firm were not signed by anyone, and it is not possible to know whether these purchase orders were formally accepted by both parties. Therefore, the Committee has	

decided to seek the clarification in this regard from the firm.

Case No.	119 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	ABRYL LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005699AM24
RA File Number	30AX04000242 AM24
Licence No and Date	3011004161/15/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Phentolamine Mesilate Injection 10mg/ml, 1 ml vial	1 Number	1	Phentolamine Mesylate	11 mg/ml

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

Case No.	120 / NC/3/MEET/Jun/202425/6
Case Status	Case Deferred
Party Name	WEXFORD LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005719AM24
RA File Number	07AX04000904 AM24
Licence No and Date	0711009215/15/09/2023

Norms Committee Decision:

The case is under consideration and TE was requested to expedite his comments.

Case No.	121 / NC/3/MEET/Jun/202425/6
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 6 and 01/07/2024
HQ File Number	HQRNORM APPLY 00005750AM24
RA File Number	08AX04001120 AM24
Licence No and Date	0811009407/19/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CANDESARTAN CILEXETIL 2 MG TABLETS	1 Number	1	CANDESARTAN CILEXETIL PH.EUR	2.04 mg
CANDESARTAN CILEXETIL 4 MG TABLETS	1 Number	2	CANDESARTAN CILEXETIL PH.EUR	4.08 mg
CANDESARTAN CILEXETIL 8 MG TABLETS	1 Number	3	CANDESARTAN CILEXETIL PH.EUR	8.16 mg
CANDESARTAN CILEXETIL 16 MG TABLETS	1 Number	4	CANDESARTAN CILEXETIL PH.EUR	16.32 mg
CANDESARTAN CILEXETIL 32 MG TABLETS	1 Number	5	CANDESARTAN CILEXETIL PH.EUR	32.64 mg
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 8MG+12.5MG	1 Number	6	CANDESARTAN CILEXETIL PH.EUR	8.16 mg
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 16MG+12.5MG	1 Number	7	CANDESARTAN CILEXETIL PH.EUR	16.32 mg

CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32MG+12.5MG	1 Number	8	CANDESARTAN CILEXETIL PH.EUR	32.64 mg
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32MG+25MG	1 Number	9	CANDESARTAN CILEXETIL PH.EUR	32.64 mg
RA concerned may take further necessary action as per above decision of NC.				