



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

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

(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Dec/202425/12

DATED: 10/12/2024

Please Note

- I. For information of exporters, Norms Committee - III handles all cases pertaining to fixation/ratification of norms for Export Products falling under ITC (HS) Chapter 29, 30 .Communications in respect of cases/pertaining to NC- III may be sent to email address: nc3.dgft@nic.in
- II. The Norms Committee has taken decision only with respect to technical aspect/wastage norms. While redeeming the applications, RAs should check that the applicant has fulfilled all requirements as prescribed in policy/procedure including those in Policy Circulars issued from time to time or any other provisions under FTP/HBP for EODC.
- III. Wherever the Committee has fixed Norms, the concerned RA may ensure that AA is issued on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less.
- 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 regard, full compliance of the 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/Dec/202425/12 dated 10/12/2024 of Norms Committee - III for the year 2024-25 was held on 10/12/2024 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	Consultant (Pharma)
4	Shri Shaish Kumar, Technical Expert	Consultant (Chemical)
5	Shri Nand Lal, Technical Expert	Consultant (Chemical)
6	Shri Uttam Dey Sarkar, ASO	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	STRIDES ALATHUR PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00093217AM21
RA File Number	09AA04004604 AM21
Licence No and Date	0911000444/26/02/2021

Norms Committee Decision:

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.
Memantine Hydrochloride Tablets USP 5Mg- 60's	1 Number	1	Memantine Hydrochloride USP	5.10 mg.
		2	Silicified Microcrystalline Cellulose (Prosolv SMCC 90)	197.00 mg.
		3	Croscarmellose Sodium (Ac Di Sol)	3.00 mg.
		4	Colloidal Silicon dioxide (Aerosil-200)	1.50 mg
		5	Magnesium Stearate (Mallinckrodt 2257)	1.50 mg.
Memantine Hydrochloride Tablets USP 5Mg- 500's	1 Number	6	Memantine Hydrochloride USP	5.10 mg.
		7	Silicified Microcrystalline Cellulose (Prosolv SMCC 90)	197.00 mg.
		8	Croscarmellose Sodium (Ac Di Sol)	3.00 mg.

		9	Colloidal Silicon dioxide (Aerosil-200)	1.50 mg.
		10	Magnesium Stearate (Mallinckrodt 2257)	1.50 mg.
Memantine Hydrochloride Tablets USP -10Mg-60's	1 Number	11	Memantine Hydrochloride USP	10.20 mg.
		12	Silicified Microcrystalline Cellulose (Prosolv SMCC 90)	192.00 mg.
		13	Croscarmellose Sodium (Ac Di Sol)	3.00 mg.
		14	Colloidal Silicon dioxide (Aerosil-200)	1.50 mg.
		15	Magnesium Stearate (Mallinckrodt 2257)	1.50 mg.
Memantine Hydrochloride Tablets USP -10Mg-500's	1 Number	16	Memantine Hydrochloride USP	10.20 mg.
		17	Silicified Microcrystalline Cellulose (Prosolv SMCC 90)	192.00 mg.
		18	Croscarmellose Sodium (Ac Di Sol)	3.00 mg.
		19	Colloidal Silicon dioxide (Aerosil-200)	1.50 mg.
		20	Magnesium Stearate (Mallinckrodt 2257)	1.50 mg.

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

Case No.	2 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00003358AM23
RA File Number	03AX04002988 AM23
Licence No and Date	0311018145/25/09/2022

Norms Committee Decision:

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.
diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	0.56 kg.
		2	Lithium Metal	0.075 kg.
		3	n-Heptane	0.89 kg.
		4	Ethyl Isobutyrate	0.374 kg.
		5	1 Bromo-5-chloropentane	0.60 kg.
		6	Methyl-ethyl-ketone	0.52 kg.
		7	N, N Dimethylacetamide	0.84 kg.
		8	Sodium t-pentoxide	0.31 kg.
		9	Iodine	0.45 kg.
		10	Tosmic	0.28 kg.

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

Case No.	3 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00006770AM23
RA File Number	03AX04005861 AM23
Licence No and Date	0311021934/06/03/2023

Norms Committee Decision:

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.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	0.56 kg.
		2	N-Heptane	0.89 kg.
		3	Ethyl Isobutyrate	0.374 kg.
		4	1 Bromo-5-chloropentane	0.60 kg.
		5	N, N Dimethylacetamide	0.84 kg.
		6	Sodium t-pentoxide	0.31 kg.
		7	Tosmic	0.28 kg.

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

Case No.	4 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001097AM24
RA File Number	03AX04000687 AM24
Licence No and Date	0311023887/25/05/2023

Norms Committee Decision:

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.
N-METHYL-2-OXO-2-PHENYLACETAMIDE	40000 kg.	1	ETHYL PHENYL GLYOXYLATE (OXOBENZENE ACETATE)	72000 kg.

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

Case No.	5 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00007460AM24
RA File Number	03AX04004237 AM24
Licence No and Date	0311029470/19/12/2023

Norms Committee Decision:

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.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate (CION-4)	1 kg.	1	Tetrahydrofuran	0.56 kg.
		2	Lithium Metal	0.075 kg.
		3	n-Heptane	0.89 kg.
		4	Ethyl Isobutyrate	0.374 kg.
		5	1 Bromo-5-chloropentane	0.60 kg.

		6	Methyl-ethyl-ketone	0.52 kg.
		7	N, N Dimethylacetamide	0.84 kg.
		8	Sodium t-pentoxide	0.31 kg.
		9	Iodine	0.45 kg.
		10	Tosmic	0.28 kg.

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

Case No.	6 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00008057AM24
RA File Number	03AX04004728 AM24
Licence No and Date	0311030291/19/01/2024

Norms Committee Decision:

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.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	0.56 kg.
		2	Lithium Metal	0.075 kg.
		3	n-Heptane	0.89 kg.
		4	Ethyl Isobutyrate	0.374 kg.
		5	1 Bromo-5-chloropentane	0.60 kg.

		6	Methyl-ethyl-ketone	0.52 kg.
		7	N, N Dimethylacetamide	0.84 kg.
		8	Sodium t-pentoxide	0.31 kg.
		9	Iodine	0.45 kg.
		10	Tosmic	0.28 kg.

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

Case No.	7 / NC/3/MEET/Dec/202425/12										
Case Status	Case Approved										
Party Name	OC SPECIALITIES PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024										
HQ File Number	HQRNORM APPLY 00008154AM24										
RA File Number	03AX04004736 AM24										
Licence No and Date	0311030436/25/01/2024										
Norms Committee Decision:											
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>N N Diisopropylethyl Amine</td><td>100000 kg.</td><td>1</td><td>Di IsoPropylAmine</td><td>100000 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	N N Diisopropylethyl Amine	100000 kg.	1	Di IsoPropylAmine	100000 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
N N Diisopropylethyl Amine	100000 kg.	1	Di IsoPropylAmine	100000 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	8 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	DCM SHRIRAM INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024																									
HQ File Number	HQRNORM APPLY 00009276AM24																									
RA File Number	05AX04003886 AM24																									
Licence No and Date	0511024653/22/03/2024																									
Norms Committee Decision:																										
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="5">D (-) Para Hydroxy Phenyl Glycine Methyl Ester</td> <td rowspan="5">1 kg.</td> <td>1</td> <td>Glyoxylic Acid (50%)</td> <td>2.044 kg.</td> </tr> <tr> <td>2</td> <td>Phenol</td> <td>1.298 kg.</td> </tr> <tr> <td>3</td> <td>Sulfamic Acid</td> <td>1.34 kg.</td> </tr> <tr> <td>4</td> <td>Acetone</td> <td>0.18 kg.</td> </tr> <tr> <td>5</td> <td>Activated Carbon</td> <td>0.035 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	D (-) Para Hydroxy Phenyl Glycine Methyl Ester	1 kg.	1	Glyoxylic Acid (50%)	2.044 kg.	2	Phenol	1.298 kg.	3	Sulfamic Acid	1.34 kg.	4	Acetone	0.18 kg.	5	Activated Carbon	0.035 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																						
D (-) Para Hydroxy Phenyl Glycine Methyl Ester	1 kg.	1	Glyoxylic Acid (50%)	2.044 kg.																						
		2	Phenol	1.298 kg.																						
		3	Sulfamic Acid	1.34 kg.																						
		4	Acetone	0.18 kg.																						
		5	Activated Carbon	0.035 kg.																						
RA concerned may take further necessary action as per above decision of NC.																										

Case No.	9 / NC/3/MEET/Dec/202425/12								
Case Status	Case Approved								
Party Name	BLUE JET HEALTHCARE LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024								
HQ File Number	HQRNORM APPLY 00000349AM25								
RA File Number	03AX04000120 AM25								
Licence No and Date	0311033250/22/04/2024								
Norms Committee Decision:									
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.					

1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	0.56 kg.
		2	N-Heptane	0.89 kg.
		3	Ethyl Isobutyrate	0.374 kg.
		4	1 Bromo-5-chloropentane	0.60 kg.
		5	N, N Dimethylacetamide	0.84 kg.
		6	Sodium t-pentoxide	0.31 kg.
		7	Tosmic	0.28 kg.

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

Case No.	10 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00000348AM25
RA File Number	03AX04000076 AM25
Licence No and Date	0311033249/22/04/2024

Norms Committee Decision:

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.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	0.56 kg.
		2	N-Heptane	0.89 kg.
		3	Ethyl Isobutyrate	0.374 kg.

		4	1 Bromo-5-chloropentane	0.60 kg.
		5	N, N Dimethylacetamide	0.84 kg.
		6	Sodium t-pentoxide	0.31 kg.
		7	Tosmic	0.28 kg.

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

Case No.	11 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00000951AM25
RA File Number	03AX04000876 AM25
Licence No and Date	0311034159/28/05/2024

Norms Committee Decision:

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.
Calcitonin Salmon Injection USP 400 I.U./2ml (200 I.U./ml)(Each ml contains : Calcitonin Salmon USP 200 I.U. Phenol USP 5mg)	1 Number	1	Calcitonin Salmon USP	0.0734 mg.

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

Case No.	12 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred

Party Name	APTRA SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00000952AM25
RA File Number	26AX04000006 AM25
Licence No and Date	2611001464/28/05/2024
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it appears that export item is non-existing and no norms can be fixed for such export. Hence, it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant information / documents:	

Case No.	13 / NC/3/MEET/Dec/202425/12													
Case Status	Case Approved													
Party Name	FDC LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024													
HQ File Number	HQRNORM APPLY 00000954AM25													
RA File Number	03AX04000939 AM25													
Licence No and Date	0311034175/28/05/2024													
Norms Committee Decision:														
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>GENTAMICIN EYE/EAR DROPS 5 ML((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.015 GM NET WT OF BULK DRUG IS 10.391 KGS))</td><td>692750 Vials</td><td>1</td><td>GENTAMICIN SULPHATE</td><td>12.725 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	GENTAMICIN EYE/EAR DROPS 5 ML((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.015 GM NET WT OF BULK DRUG IS 10.391 KGS))	692750 Vials	1	GENTAMICIN SULPHATE	12.725 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
GENTAMICIN EYE/EAR DROPS 5 ML((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.015 GM NET WT OF BULK DRUG IS 10.391 KGS))	692750 Vials	1	GENTAMICIN SULPHATE	12.725 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	14 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00000957AM25
RA File Number	08AX04000294 AM25
Licence No and Date	0811011676/28/05/2024

Norms Committee Decision:

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 FREE BASE API (BULK DRUG)	1 kg.	1	(R)-3-[(tert-butoxycarbonyl)amino-4-(2,4,5-trifluorophenyl)]butanoic acid	0.953 kg.
		2	3-(trifluoromethyl)-5,6,7,8-tetrahydro [1,2,4] triazolo [4,3-a]pyrazine hydrochloride	0.686 kg.
		3	O-(Benzotriazol-1-yl)-N,N,N',N'-tetramethyluronium Tetrafluoroborate (TBTU)	0.936 kg.
		4	ISOPROPYL ALCOHOL	6.80 kg.
		5	METHANOL	5.25 kg.

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

Case No.	15 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	MANIPAL NATURAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00000966AM25
RA File Number	07AX04000258 AM25
Licence No and	0711011405/28/05/2024

Date	
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete Certificate of Analysis (CoA) of import items from supplier indicating mesh size. 2. Specification of export indicating mesh size.	

Case No.	16 / NC/3/MEET/Dec/202425/12														
Case Status	Case Approved														
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED														
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024														
HQ File Number	HQRNORM APPLY 00000994AM25														
RA File Number	03AX04000906 AM25														
Licence No and Date	0311034224/29/05/2024														
Norms Committee Decision:															
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. 0311023871 dated 25/05/2023 , 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>AMANTADINE HYDROCHLORIDE 100 MG CAPSULES (DINETREL100 MG)</td><td>1 Number Capsule</td><td>1</td><td>AMANTADINE HYDROCHLORIDE</td><td>102 mg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	AMANTADINE HYDROCHLORIDE 100 MG CAPSULES (DINETREL100 MG)	1 Number Capsule	1	AMANTADINE HYDROCHLORIDE	102 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.											
AMANTADINE HYDROCHLORIDE 100 MG CAPSULES (DINETREL100 MG)	1 Number Capsule	1	AMANTADINE HYDROCHLORIDE	102 mg.											
RA concerned may take further necessary action as per above decision of NC.															

Case No.	17 / NC/3/MEET/Dec/202425/12			
Case Status	Case Approved			
Party Name	ALEMBIC PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024			
HQ File Number	HQRNORM APPLY 00000977AM25			
RA File Number	08AX04000298 AM25			

Licence No and Date	0811011681/29/05/2024			
Norms Committee Decision:				
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.
Loteprednol Etabonate & Tobramycin Ophthalmic suspension 0.5%/ 0.3% - 5 ML	1 Number	1	Loteprednol Etabonate Sterile Micronized	25.50 mg.
		2	Tobramycin USP	15.30 mg.
Loteprednol Etabonate & Tobramycin Ophthalmic suspension 0.5%/ 0.3% - 10 ML	1 Number	3	Loteprednol Etabonate Sterile Micronized	51.00 mg.
		4	Tobramycin USP	30.60 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	18 / NC/3/MEET/Dec/202425/12			
Case Status	Case Approved			
Party Name	FINE ORGANIC INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024			
HQ File Number	HQRNORM APPLY 00000978AM25			
RA File Number	03AX04000881 AM25			
Licence No and Date	0311034209/29/05/2024			
Norms Committee Decision:				
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.
Sodium Stearyl Lactylate (Fatty Acid Ester)	1 kg.	1	Lactic Acid	0.295 kg.

		2	Stearic Acid	0.765 kg.
--	--	---	--------------	-----------

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

Case No.	19 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	AGIO PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00000990AM25
RA File Number	03AX04000815 AM25
Licence No and Date	0311034218/29/05/2024

Norms Committee Decision:

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

- 1. Copy of Drug Manufacturing Licence (DML).**
- 2. Import quantity against each export product pack size.**

Case No.	20 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	SAGA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00000999AM25
RA File Number	08AX04000285 AM25
Licence No and Date	0811011704/29/05/2024

Norms Committee Decision:

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.
LYSINE CLONIXINATE (125MG)	500000	1	CLONIXINATE	63.75 kg.

AND PROPINOX HYDROCHLORIDE (10MG) TABLETS (CONTENTS OF CLONIXINATE LYSINE 62.50 KGS)	Numbers		LYSINE	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	21 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	GULBRANDSEN INDUSTRIES LLP
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001000AM25
RA File Number	34AX04000145 AM25
Licence No and Date	3411004994/29/05/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical reaction indicating molecular weight of Reactant and Products. 2. Step wise and overall yield of the reaction. 3. End use of export item and a copy of minutes, if approved in the past by Norms Committee.	

Case No.	22 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	SAI RAM CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001002AM25
RA File Number	26AX04000011 AM25
Licence No and Date	2611001466/29/05/2024
Norms Committee Decision: 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.
(4R-CIS)-1,1-Dimethylethyl-6-(2-Aminomethyl-2,2-Dimethyl-1,3-Dioxane-4-Acetate (Amino Ketal)	1 kg.	1	(4R,Cis)-1,1-Dimethylethyl-6-Cyanomethyl-2,2-Dimethyl-1,3-Dioxane-4-Acetate	1.01 kg.

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

Case No.	23 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001017AM25
RA File Number	03AX04000988 AM25
Licence No and Date	0311034260/30/05/2024

Norms Committee Decision:

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.
(4R-Cis)-1,1-dimethylethyl 6-{2[2-(4-fluorophenyl)-5-(1-methylethyl)-3-phenyl-4[(phenylamino) carbonyl](1H-pyrrol-1-yl) ethyl]-2,2-dimethyl-1,3-dioxan-4-acetate (ATV-1))	1 kg.	1	Diisopropyl Amine	0.50 kg.

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

Case No.	24 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001018AM25
RA File Number	03AX04000989 AM25
Licence No and Date	0311034261/30/05/2024

Norms Committee Decision:

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.
Atorvastatin Calcium	1 kg.	1	(4R-Cis)-1,1-dimethylethyl 6-{2-[2-(4-fluorophenyl)-5-(1-isopropyl)-3-phenyl-	0.6259 kg.
		2	METHANOL	4.285 kg.

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

Case No.	25 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	AARTI PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001028AM25
RA File Number	03AX04000079 AM25
Licence No and Date	0311034279/31/05/2024

Norms Committee Decision:

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

1. **Manufacturing process giving chemical reaction indicating molecular weight of Reactant and Products and import of item S03 is in solid or liquid form.**
2. **Step wise and overall yield of the reaction with justification.**
3. **Specific requirement of import item 1 i.e Ethyl alcohol or Denatured Ethyl alcohol.**
4. **A copy of Minutes, if approved in the past by Norms Committee.**

Case No.	26 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001066AM25
RA File Number	05AX04000713 AM25
Licence No and Date	0511025847/03/06/2024

Norms Committee Decision:

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.
Tobramycin Inhalation Solution, 300mg/ 4ml(Having net content of 49.26 kg of Bulk drug (filling volume 4.35ml in each number))	151000 Numbers	1	TOBRAMYCIN USP	47.565 kg.

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

Case No.	27 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001061AM25
RA File Number	05AX04000712 AM25
Licence No and Date	0511025839/03/06/2024

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.
Nitroglycerin Sublingual Tablets USP, 0.3mg	1 Number	1	DILUTED NITROGLYCERIN USP (2% W/W)	15.30 mg.
Nitroglycerin Sublingual Tablets USP, 0.4mg	1 Number	2	DILUTED NITROGLYCERIN USP (2% W/W)	20.40 mg.
Nitroglycerin Sublingual Tablets USP, 0.6mg	1 Number	3	DILUTED NITROGLYCERIN USP (2% W/W)	30.60 mg.

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

Case No.	28 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001058AM25
RA File Number	08AX04000327 AM25
Licence No and	0811011729/03/06/2024

Date														
Norms Committee Decision:														
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. 0811008290 dated 25/05/2023 , 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 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>CAPTOPRIL TABLETS USP -25 MG (ANGIOPRIL 25 MG)((each uncoated tablet contains USP 25mg.</td> <td>1 Number</td> <td>1</td> <td>CAPTOPRIL USP</td> <td>25.50 mg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CAPTOPRIL TABLETS USP -25 MG (ANGIOPRIL 25 MG)((each uncoated tablet contains USP 25mg.	1 Number	1	CAPTOPRIL USP	25.50 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
CAPTOPRIL TABLETS USP -25 MG (ANGIOPRIL 25 MG)((each uncoated tablet contains USP 25mg.	1 Number	1	CAPTOPRIL USP	25.50 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	29 / NC/3/MEET/Dec/202425/12								
Case Status	Case Approved								
Party Name	STERILE INDIA PRIVATE LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024								
HQ File Number	HQRNORM APPLY 00001126AM25								
RA File Number	05AX04000637 AM25								
Licence No and Date	0511025895/05/06/2024								
Norms Committee Decision:									
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/Jun/202324/8 dated 30/06/2023 against advance authorization No. 0511017736 dated 14/03/2023 , 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 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.					

Deferoxamine Mesylate Lyophilized Sterile	1 kg.	1	Deferoxamine Mesylate USP (Non-Sterile)	1.02 kg.
---	-------	---	---	----------

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

Case No.	30 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	DR.ACHARYA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001119AM25
RA File Number	03AX04000976 AM25
Licence No and Date	0311034156/05/06/2024

Norms Committee Decision:

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.
3-Methoxy-2-methylbenzoyl chloride (MMBC)(CAS No.: 24487-91-0)	1 kg.	1	3-Methoxy-o-toluic Acid (MOTA)	0.95 kg.

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

Case No.	31 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	CLARIANT INDIA PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024

and Date	
HQ File Number	HQRNORM APPLY 00001120AM25
RA File Number	03AX04001111 AM25
Licence No and Date	0311034385/05/06/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. The norms for the export item was approved through raw material Hydroxyl Amine Hydrochloride and other chemicals, therefore, difference in the present item of import Hydroxyl ammonium sulfate. 2. Stoichiometric material balance of the reaction on molar basis. 3. The commercial value of by-products obtained during reaction. 4. Overall yield of reaction with justification for the low yield.	

Case No.	32 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	MOREPEN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001122AM25
RA File Number	05AX04000723 AM25
Licence No and Date	0511025891/05/06/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Export product is not matching with chemistry given for stage 3(DP06). 2. Percentage yield on molar basis for each step. 3. Recovery of solvent at each stage.	

Case No.	33 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred

Party Name	MOREPEN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001123AM25
RA File Number	05AX04000722 AM25
Licence No and Date	0511025892/05/06/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	34 / NC/3/MEET/Dec/202425/12			
Case Status	Case Approved			
Party Name	AASTRID LIFE SCIENCES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024			
HQ File Number	HQRNORM APPLY 00001124AM25			
RA File Number	03AX04001065 AM25			
Licence No and Date	0311034388/05/06/2024			
Norms Committee Decision:				
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.	35 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	MICRO LABS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001148AM25
RA File Number	07AX04000379 AM25
Licence No and Date	0711011477/06/06/2024

Norms Committee Decision:

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. 0711006198 dated 16/01/2023** , 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.
AMOXICILLIN 250 MG + FLUCLOXACILLIN 250 MG CAPSULES - 1999.985 KGS)	1 Number Capsule	1	AMOXICILLIN TRIHYDRATE BP/EP/IP/USP	292.68 mg/Capsule
		2	FLUCLOXACILLIN SODIUM BP/EP/IP/USP	277.47 mg/Capsule
AMOXICILLIN 125 MG + FLUCLOXACILLIN 125 MG /5ML ORAL SUSPENSION 100ML BOTTLES - 350.00 KGS)	1 Number Bottle	3	AMOXICILLIN TRIHYDRATE BP/EP/IP/USP	3012.83 mg/Bottle
		4	FLUCLOXACILLIN SODIUM BP/EP/IP/USP	2856.33 mg/Bottle

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

Case No.	36 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001149AM25
RA File Number	07AX04000378 AM25
Licence No and Date	0711011478/06/06/2024

Norms Committee Decision:

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/Jun/202425/6 dated 01/07/2024** against advance authorization **No. 0811009157 dated 21/08/2023**, 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 INJECTION SOLUTION 1000MG/10ML (196.50 KGS)	1 Number	1	TRANEXAMIC ACID USP	1.05 gm/100 ml Vial

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

Case No.	37 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001150AM25
RA File Number	07AX04000380 AM25
Licence No and Date	0711011479/06/06/2024

Norms Committee Decision:

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/202425/9 dated 10/10/2024** against advance authorization **No. 0711006102 dated 05/01/2023**, 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.
DICLOXACILLIN CAPSULES 250MG (65.003 KGS))	1 Number	1	DICLOXACILLIN SODIUM E.P	267.5 mg/250 mg Capsule

DICLOXACILLIN CAPSULES 500MG (1629.995 KGS))	1 Number	2	DICLOXACILLIN SODIUM E.P	535.0 mg/500 mg Capsule
---	----------	---	--------------------------	----------------------------

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

Case No.	38 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	ANNORA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001157AM25
RA File Number	09AX04000088 AM25
Licence No and Date	0911007356/06/06/2024

Norms Committee Decision:

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.
Sucralfate Oral Suspension 1 g / 10 ML 420 ML (Composition : Each 10 mL of Suspension Contains, Sucralfate USP 1g)	106973 Numbers	1	Sucralfate USP	4717.51 kg.

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

Case No.	39 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024

and Date														
HQ File Number	HQRNORM APPLY 00001164AM25													
RA File Number	09AX04000161 AM25													
Licence No and Date	0911007369/06/06/2024													
Norms Committee Decision:														
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>Cefepime for Injection 1 Gram (Each vial contains Sterile mixture of Cefepime Hydrochloride USP Equivalent to Cefepime 1 gram and L-Arginine for pH adjustment (as a buffer))</td> <td>1 Number</td> <td>1</td> <td>Sterile Cefepime with Arginine</td> <td>1.8975 gm</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Cefepime for Injection 1 Gram (Each vial contains Sterile mixture of Cefepime Hydrochloride USP Equivalent to Cefepime 1 gram and L-Arginine for pH adjustment (as a buffer))	1 Number	1	Sterile Cefepime with Arginine	1.8975 gm
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Cefepime for Injection 1 Gram (Each vial contains Sterile mixture of Cefepime Hydrochloride USP Equivalent to Cefepime 1 gram and L-Arginine for pH adjustment (as a buffer))	1 Number	1	Sterile Cefepime with Arginine	1.8975 gm										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	40 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001166AM25
RA File Number	08AX04000371 AM25
Licence No and Date	0811011769/07/06/2024
Norms Committee Decision:	
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/Feb/202324/23 dated 19/02/2024 against advance authorization No. 0811009604 dated 09/10/2023, 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.
BISOPROLOL FUMARATE TABLETS 1.25 MG(EACH FILM COATED TABLET CONTAINS: BISOPROLOL FUMARATE USP 1.25 MG NET CONTENT OF BISOPROLOL FUMARATE SHOULD NOT BE LESS THAN 5.530 KG IN EXPORT ITEM.)	1 Number Tablet	1	BISOPROLOL FUMARATE USP	1.275 mg/1.25 mg Tablet
BISOPROLOL FUMARATE TABLETS 2.5 MG(EACH FILM COATED TABLET CONTAINS: BISOPROLOL FUMARATE USP 2.5 MG NET CONTENT OF BISOPROLOL FUMARATE SHOULD NOT BE LESS THAN 14.978 KG IN EXPORT ITEM.)	1 Number Tablet	2	BISOPROLOL FUMARATE USP	2.55 mg/2.5 mg Tablet
BISOPROLOL FUMARATE TABLETS 5 MG(EACH FILM COATED TABLET CONTAINS: BISOPROLOL FUMARATE USP 5 MG NET CONTENT OF BISOPROLOL FUMARATE SHOULD NOT BE LESS THAN 29.850 KG IN EXPORT ITEM.)	1 Number Tablet	3	BISOPROLOL FUMARATE USP	5.10 mg/5 mg Tablet
BISOPROLOL FUMARATE TABLETS 10 MG(EACH FILM COATED TABLET CONTAINS: BISOPROLOL FUMARATE USP 10 MG NET CONTENT OF BISOPROLOL FUMARATE SHOULD NOT BE	1 Number Tablet	4	BISOPROLOL FUMARATE USP	10.20 mg/10 mg Tablet

LESS THAN 43.970 KG IN EXPORT ITEM.)				
--------------------------------------	--	--	--	--

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

Case No.	41 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001174AM25
RA File Number	03AX04001084 AM25
Licence No and Date	0311034440/07/06/2024

Norms Committee Decision:

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/Nov/202425/10 dated 22/11/2024** against advance authorization **No. 0311033608 dated 06/05/2024**, 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.
ROSUVASTATIN TABLET BP / USP 10 MG.((Each Tablet contains Rosuvastatin Calcium 10.400 mg) Eq. to Rosuvastatin 10 mg.	52500000 Numbers	1	Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate	556.92 kg.

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

Case No.	42 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001197AM25
RA File Number	07AX04000407 AM25
Licence No and Date	0711011510/08/06/2024

Norms Committee Decision:

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/202425/2 dated 30/04/2024** against advance authorization **No. 0711008298 dated 19/06/2023**, 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.
AZELASTINE HYDROCHLORIDER EYE DROPS SOLUTION 0.05% weight by volume	1 Number	1	AZELASTINE HYDROCHLORIDE Ph.Eur	5.10 mg/10 ml Vial

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

Case No.	43 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001242AM25
RA File Number	05AX04000783 AM25
Licence No and Date	0511026035/11/06/2024

Norms Committee Decision:

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

1. **Manufacturing process in detail.**
2. **Complete chemistry with Stoichiometric balance molecular weight and percentage of yield.**

Case No.	44 / NC/3/MEET/Dec/202425/12										
Case Status	Case Approved										
Party Name	MICRO LABS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024										
HQ File Number	HQRNORM APPLY 00001241AM25										
RA File Number	07AX04000435 AM25										
Licence No and Date	0711011543/11/06/2024										
Norms Committee Decision:											
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. 2/82-ALC4/2020 dated 10/07/2020 against advance authorization No. 0310826799 dated 04/02/2019, 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>BROMOCRIPTINE TABLETS 2.5mg</td><td>1 Number</td><td>1</td><td>BROMOCRIPTINE MESILATE BP/EP/IP/USP</td><td>2.927 mg/Tablet.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	BROMOCRIPTINE TABLETS 2.5mg	1 Number	1	BROMOCRIPTINE MESILATE BP/EP/IP/USP	2.927 mg/Tablet.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
BROMOCRIPTINE TABLETS 2.5mg	1 Number	1	BROMOCRIPTINE MESILATE BP/EP/IP/USP	2.927 mg/Tablet.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	45 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	ALCHEMIE FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001248AM25
RA File Number	03AX04001154 AM25

Licence No and Date	0311034547/12/06/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Stoichiometric material balance of the reaction on molar basis. 2. Stage wise yield of the reaction indicating overall yield with justification for the low yield.	

Case No.	46 / NC/3/MEET/Dec/202425/12													
Case Status	Case Approved													
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024													
HQ File Number	HQRNORM APPLY 00001250AM25													
RA File Number	08AX04000413 AM25													
Licence No and Date	0811011789/12/06/2024													
Norms Committee Decision:														
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/Nov/202425/10 dated 22/11/2024 against advance authorization No. 0811010830 dated 21/02/2024, 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>Cupric Chloride Injection USP, 0.4 mg/mL (10 mL)</td><td>1 Number</td><td>1</td><td>Copper (II) chloride dihydrate GMP</td><td>11.77 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Cupric Chloride Injection USP, 0.4 mg/mL (10 mL)	1 Number	1	Copper (II) chloride dihydrate GMP	11.77 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Cupric Chloride Injection USP, 0.4 mg/mL (10 mL)	1 Number	1	Copper (II) chloride dihydrate GMP	11.77 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	47 / NC/3/MEET/Dec/202425/12
----------	------------------------------

Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001254AM25
RA File Number	08AX04000339 AM25
Licence No and Date	0811011790/12/06/2024

Norms Committee Decision:

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.
Calcium Gluconate Injection, USP 1,000 mg per 10 mL (100 mg per mL)	1 Number	1	CALCIUM GLUCONATE MONOHYDRATE USP	1081.0 mg.
Calcium Gluconate Injection, USP 5,000 mg per 50 mL (100 mg per mL)	1 Number	2	CALCIUM GLUCONATE MONOHYDRATE USP	5145.0 mg.
Calcium Gluconate Injection, USP 10,000 mg per 100 mL (100 mg per mL)	1 Number	3	CALCIUM GLUCONATE MONOHYDRATE USP	10290.0 mg.

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

Case No.	48 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001267AM25
RA File Number	03AX04001124 AM25
Licence No and Date	0311034554/12/06/2024
Norms Committee Decision:	

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.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	0.56 kg.
		2	N-Heptane	0.89 kg.
		3	Ethyl Isobutyrate	0.374 kg.
		4	1 Bromo-5-chloropentane	0.60 kg.
		5	N, N Dimethylacetamide	0.84 kg.
		6	Sodium t-pentoxide	0.31 kg.
		7	Tosmic	0.28 kg.

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

Case No.	49 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001269AM25
RA File Number	08AX04000373 AM25
Licence No and Date	0811011805/12/06/2024
Norms Committee Decision:	
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/Feb/202324/23 dated 19/02/2024 against	

advance authorization No. **0811009604** dated **09/10/2023**, 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.
BISOPROLOL FUMARATE TABLETS 5 MG (Bisoprolol Galenika 5 mg)(Each film coated tablet contains Bisoprolol Fumarate EP 5 mg and Excipients. Net content of Bisoprolol Fumarate should not be less than 65.000 Kg in export item.)	1 Number Tablet	1	BISPROLOL FUMARATE EP	5.10 mg/5 mg Tablet
BISOPROLOL FUMARATE 10 MG TABLETS (Bisoprolol Galenika 10 mg)(Each film coated tablet contains Bisoprolol Fumarate EP 10 mg and Excipients. Net content of Bisoprolol Fumarate should not be less than 24.000 Kg in export item.)	1 Number Tablet	2	BISPROLOL FUMARATE EP	10.20 mg/10 mg Tablet

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

Case No.	50 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001270AM25
RA File Number	08AX04000356 AM25
Licence No and Date	0811011806/12/06/2024

Norms Committee Decision:

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. 0811010967 dated 04/03/2024**, 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.
PROPAFENONE TABLETS 150MG (PROPRAFENON 150 HEUMANN)(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 150 MG	1 Number	1	PROPAFENONE HYDROCHLORIDE EP	153 mg/Tablet
PROPAFENONE TABLETS 300MG (PROPRAFENON 300 HEUMANN)(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 300 MG	1 Number	2	PROPAFENONE HYDROCHLORIDE EP	306 mg/Tablet

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

Case No.	51 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001279AM25
RA File Number	05AX04000655 AM25
Licence No and Date	0511026076/13/06/2024

Norms Committee Decision:

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. 0511023989 dated 15/02/2024**, 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.
Ceftriaxone Sodium Sterile	1 kg.	1	Ceftriaxone Sodium (Non Sterile)	1.04 kg.

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

Case No.	52 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001316AM25
RA File Number	52AX04000061 AM25
Licence No and Date	5211008490/13/06/2024

Norms Committee Decision:

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

- I. Complete Chemistry indicating molecular weight of both reactant and products with yield and justification, including Hydrazine Hydrate 64% to Semicarbazide HCL.**
- II. Production consumption data (including Hydrazine Hydrate 64% to Semicarbazide HCL) for the last three years duly certified by Chartered Accountant.**

Case No.	53 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	CHEMPLAST SANMAR LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001314AM25
RA File Number	04AX04000189 AM25
Licence No and Date	0411007575/13/06/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. The commercial value of by-product formed during 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 Chartered Accountant.	

Case No.	54 / NC/3/MEET/Dec/202425/12										
Case Status	Case Approved										
Party Name	OC SPECIALITIES PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024										
HQ File Number	HQRNORM APPLY 00001311AM25										
RA File Number	03AX04001155 AM25										
Licence No and Date	0311034601/13/06/2024										
Norms Committee Decision:											
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> </td><td> </td><td> </td><td> </td><td> </td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							

DMA Chloride-Lan	40000 kg.	1	2-Chloro Benzyl Chloride	44000 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	55 / NC/3/MEET/Dec/202425/12													
Case Status	Case Approved													
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024													
HQ File Number	HQRNORM APPLY 00001276AM25													
RA File Number	03AX04000955 AM25													
Licence No and Date	0311034567/13/06/2024													
Norms Committee Decision:														
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/202324/13 dated 14/09/2023 against advance authorization No. 0311025247 dated 10/07/2023, 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>FAROPENEM SODIUM</td><td>1 kg.</td><td>1</td><td>(3R,4R)-4-ACETOXY-3-[(R)-1-(T-BUTYLDIMETHYLSILYLOXY)ETHYL]-2-AZITIDINONE;4-AA(AOSA)</td><td>1.20 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	FAROPENEM SODIUM	1 kg.	1	(3R,4R)-4-ACETOXY-3-[(R)-1-(T-BUTYLDIMETHYLSILYLOXY)ETHYL]-2-AZITIDINONE;4-AA(AOSA)	1.20 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
FAROPENEM SODIUM	1 kg.	1	(3R,4R)-4-ACETOXY-3-[(R)-1-(T-BUTYLDIMETHYLSILYLOXY)ETHYL]-2-AZITIDINONE;4-AA(AOSA)	1.20 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	56 / NC/3/MEET/Dec/202425/12			
Case Status	Case Deferred			
Party Name	ETERNIS FINE CHEMICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024			
HQ File Number	HQRNORM APPLY 00001292AM25			

RA File Number	03AX04001135 AM25
Licence No and Date	0311034573/13/06/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical name of export item and to indicate difference in norms approved in the past for the export item (Ambercore) and other names. 2. Chemistry indicating molecular weight of reactants and products with yield. 3. End use of export item.	

Case No.	57 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001293AM25
RA File Number	03AX04001186 AM25
Licence No and Date	0311034574/13/06/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Manufacturing process using methanol as input giving chemistry indicating molecular weight of reactants and product with yield and justification. 2. Stoichiometric material balance of the item of export on molar basis. 3. End use of export item.	

Case No.	58 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	LINCOLN PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024

HQ File Number	HQRNORM APPLY 00001296AM25
RA File Number	08AX04000313 AM25
Licence No and Date	0811011811/13/06/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	59 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001308AM25
RA File Number	03AX04001160 AM25
Licence No and Date	0311034428/13/06/2024

Norms Committee Decision:

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.
MOXILEB KID TABLET (AMOXICILLIN TABLET 125MG)((EACH TABLET CONTAINING AMOXICILLIN TRIHYDRATE EQUIVALENT TO 125MG OF AMOXICILLIN) NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE BP (COMPACTED) 71.751 KGS (EXCL 2% WASTAGE))	500000 Tablets	1	AMOXICILLIN TRIHYDRATE BP COMPACTED	73.16 kg
MOXILEB-250 CAPSULE. (AMOXICILLIN CAPSULES	4200000 Capsules	2	AMOXICILLIN TRIHYDRATE BP COMPACTED	1229.085 kg.

250MG)((EACH CAPSULE CONTAINING AMOXICILLIN TRIHYDRATE EQUIVALENT TO 250MG OF AMOXICILLIN). NET CONTENT OF IMPORT/ EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE BP (COMPACTED) - 1205.400 KGS (EXCLUDING 2% WASTAGE))				
MOXILEB-500 CAPSULE. (AMOXICILLIN CAPSULES 500MG)((EACH CAPSULE CONTAINING AMOXICILLIN TRIHYDRATE EQUIVALENT TO 500 MG OF AMOXICILLIN). NET CONTENT OF IMPORT /EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE BP (COMPACTED) - 3624.810 KGS (EACLUDING 2% WASTAGE))	6315000 Capsules	3	AMOXICILLIN TRIHYDRATE BP COMPACTED	3696.036 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	60 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001309AM25
RA File Number	03AX04001212 AM25
Licence No and Date	0311034498/13/06/2024
Norms Committee Decision:	

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

Case No.	61 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	SUPRIYA LIFESCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001310AM25
RA File Number	03AX04001271 AM25
Licence No and Date	0311034600/13/06/2024

Norms Committee Decision:

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.
RIBOFLAVIN SODIUM PHOSPHATE HYDRATE EP 11.2	1 kg	1	VITAMIN B2 OR RIBOFLAVIN	1.17 kg.
		2	PYRIDINE	2.00 kg.
		3	ACETONITRILE	1.73 kg.
		4	PHOSPHORUS OXYCHLORIDE	2.00 kg.

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

Case No.	62 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024

and Date	
HQ File Number	HQRNORM APPLY 00001312AM25
RA File Number	03AX04001280 AM25
Licence No and Date	0311034602/13/06/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	63 / NC/3/MEET/Dec/202425/12										
Case Status	Case Approved										
Party Name	WEST BENGAL CHEMICAL INDUSTRIES LTD.										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024										
HQ File Number	HQRNORM APPLY 00001344AM25										
RA File Number	02AX04000161 AM25										
Licence No and Date	0211006735/14/06/2024										
Norms Committee Decision:											
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>Calcium Orotate(~)</td><td>1 kg.</td><td>1</td><td>Orotic Acid</td><td>0.95 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Calcium Orotate(~)	1 kg.	1	Orotic Acid	0.95 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Calcium Orotate(~)	1 kg.	1	Orotic Acid	0.95 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	64 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001318AM25

RA File Number	03AX04001192 AM25			
Licence No and Date	0311034620/14/06/2024			
Norms Committee Decision:				
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.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	0.56 kg.
		2	N-Heptane	0.89 kg.
		3	Ethyl Isobutyrate	0.374 kg.
		4	1 Bromo-5-chloropentane	0.60 kg.
		5	N, N Dimethylacetamide	0.84 kg.
		6	Sodium t-pentoxide	0.31 kg.
		7	Tosmic	0.28 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	65 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001322AM25
RA File Number	08AX04000399 AM25
Licence No and Date	0811011827/14/06/2024
Norms Committee Decision:	

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/202425/9 dated 10/10/2024** against advance authorization **No. 0811006983 dated 11/01/2023**, 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.
Magnesium Sulfate In Water for Injection (0.325 mEq Mg ⁺⁺ /mL) 40 mg/mL 2g Total	1 Number	1	Magnesium Sulfate Heptahydrate phEur, USP	2.00 gm
Magnesium Sulfate In Water for Injection (0.325 mEq Mg ⁺⁺ /mL) 40 mg/mL 4g Total	1 Number	2	Magnesium Sulfate Heptahydrate phEur, USP	2.897 gm

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

Case No.	66 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	SANOFI INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001337AM25
RA File Number	03AX04001301 AM25
Licence No and Date	0311034648/14/06/2024

Norms Committee Decision:

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.
Ramipril PC Granules((Net	7000 kg.	1	Ramipril	6009.50 kg.

content: each 1 gm of Ramipril 850 mg, Total net content Ramipril 5950 kg))				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	67 / NC/3/MEET/Dec/202425/12													
Case Status	Case Approved													
Party Name	WEST BENGAL CHEMICAL INDUSTRIES LTD.													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024													
HQ File Number	HQRNORM APPLY 00001341AM25													
RA File Number	02AX04000159 AM25													
Licence No and Date	0211006732/14/06/2024													
Norms Committee Decision:														
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>Calcium Levulinate(~)</td><td>1 kg.</td><td>1</td><td>Levulinic Acid</td><td>0.8 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Calcium Levulinate(~)	1 kg.	1	Levulinic Acid	0.8 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Calcium Levulinate(~)	1 kg.	1	Levulinic Acid	0.8 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	68 / NC/3/MEET/Dec/202425/12			
Case Status	Case Approved			
Party Name	WEST BENGAL CHEMICAL INDUSTRIES LTD.			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024			
HQ File Number	HQRNORM APPLY 00001342AM25			

RA File Number	02AX04000158 AM25			
Licence No and Date	0211006733/14/06/2024			
Norms Committee Decision:				
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.
Ferric Citrate(~)	1 kg.	1	Citric Acid Monohydrate	0.84 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	69 / NC/3/MEET/Dec/202425/12			
Case Status	Case Approved			
Party Name	WEST BENGAL CHEMICAL INDUSTRIES LTD.			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024			
HQ File Number	HQRNORM APPLY 00001343AM25			
RA File Number	02AX04000160 AM25			
Licence No and Date	0211006734/14/06/2024			
Norms Committee Decision:				
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.
Magnesium Pidolate(~)	1 kg.	1	L-Pyrocolumatic Acid	0.968 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	70 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001379AM25
RA File Number	09AX04000169 AM25
Licence No and Date	0911007440/18/06/2024

Norms Committee Decision:

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.
Dipyridamole modified release and Acetyl Salicyclic Acid Capsules 200mg+25mg - Brand Name : Orisantin 200mg/25mg Caps(Dipyridamole modified release and Acetyl Salicyclic Acid Capsules 200mg+25mg - Brand Name : (Orisantin 200mg/25mg depotkapseli, kova/kapsel med modifierad frisattning, hard) Pack Size : 100s (Consist of 1080.08 Kgs of Dipyridamole - Ph Eur))	1 Number	1	Dipyridamole	204 mg/200 mg
Dipyridamole modified release and Acetyl Salicyclic Acid Capsules 200mg+25mg - Brand Name : Diprasorin 200/25mgCaps100s (Dipyridamole modified release and Acetyl Salicyclic Acid Capsules 200mg+25mg - Brand Name : (Diprasorin 200mg/25 mg hardkapsel med modifieradfrisattning/ hardkapsel med modifisertfr) Pack Size : 100s (Consist of 800.00 Kgs of Dipyridamole - Ph Eur))	1 Number	2	Dipyridamole	204 mg/200 mg
Dipyridamole Modified Release capsules	1 Number	3	Dipyridamole	204 mg/200 mg

200 mg Pack Size : 60s Consist of 319.97 Kgs of Dipyridamole - Ph Eur) (Dipyridamole Modified Release capsules 200 mg Pack Size : 60s Consist of 319.97 Kgs of Dipyridamole - Ph Eur)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	71 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001396AM25
RA File Number	09AX04000130 AM25
Licence No and Date	0911007445/18/06/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	72 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001408AM25
RA File Number	03AX04001311 AM25
Licence No and Date	0311034718/19/06/2024
Norms Committee Decision:	
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/Jun/202425/9 dated 14/06/2024 against advance authorization No. 0311007268 dated 28/09/2021 , 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.
BRIMONIDINE TARTRATE EYE DROPS 5 ML (IOBRIM EYE DROPS 5 ML & IOBRAM EYE DROPS 5 ML)((EACH VIAL CONTAINS BRIMONIDINE L TARTRATE 0.01 GM NET WT OF BULK DRUG IS 460 Grams))	1 Number	1	BRIMONIDINE L TARTRATE	10.2 mg.

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

Case No.	73 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001424AM25
RA File Number	08AX04000355 AM25
Licence No and Date	0811011866/19/06/2024

Norms Committee Decision:

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/Aug/202425/8 dated 28/08/2024** against advance authorization **No. 0811011226 dated 04/04/2024**, 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. Net content of active	1 Number	1	Opipramol Dihydrochloride	51 mg/Tablet

ingredient Pipramol Dihydrochloride should not be less than 100.00 kgs in export product.)				
Pipramol Dihydrochloride Tablets 100 MG (PIPRAMOL HEUMANN 100 MG)(Each film coated tablet contains:Pipramol Dihydrochloride 100 mg Excipients. q.s. Net content of active ingredient Pipramol Dihydrochloride should not be less than 100.00 kgs in export product.)	1 Number	2	Pipramol Dihydrochloride	102 mg/Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	74 / NC/3/MEET/Dec/202425/12			
Case Status	Case Approved			
Party Name	OC SPECIALITIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024			
HQ File Number	HQRNORM APPLY 00001440AM25			
RA File Number	03AX04001349 AM25			
Licence No and Date	0311034767/20/06/2024			
Norms Committee Decision:				
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.	75 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001490AM25
RA File Number	03AX04001450 AM25
Licence No and Date	0311034819/21/06/2024
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant documents.	

Case No.	76 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	AGGARWWAL EXPORTS
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001484AM25
RA File Number	05AX04000858 AM25
Licence No and Date	0511026193/21/06/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Chemistry indicating molecular weight of reactants and products with yield and justification. 2. End use of export item. 3. Stoichiometric material balance on molar basis.	

Case No.	77 / NC/3/MEET/Dec/202425/12
----------	------------------------------

Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001486AM25
RA File Number	05AX04000757 AM25
Licence No and Date	0511026265/21/06/2024

Norms Committee Decision:

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.
Brinzolamide Ophthalmic Suspension, 1% w/v 5ml (Sterile Eye Drops)((Each ml contains Brinzolamide equivalent to Brinzolamide Micronized Sterile 10 mg (Equivalent to 4500 Gm of Bulk Drug))	1 Number	1	Brinzolamide (Micronized and Sterile)	51.00 mg/Vial

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

Case No.	78 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	STERIL-GENE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001488AM25
RA File Number	04AX04001003 AM24
Licence No and Date	0411007616/21/06/2024

Norms Committee Decision:

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

Case No.	79 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001489AM25
RA File Number	03AX04001452 AM25
Licence No and Date	0311034818/21/06/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	80 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001491AM25
RA File Number	03AX04001449 AM25
Licence No and Date	0311034820/21/06/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	81 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	GULBRANDSEN INDUSTRIES LLP
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001492AM25
RA File Number	34AX04000146 AM25
Licence No and Date	3411005088/21/06/2024
Norms Committee Decision:	

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

1. **Chemical reaction indicating molecular weight of Reactant and Products.**
2. **Step wise and overall yield of the reaction.**
3. **End use of export item and copy of minutes, if approved in the past by the Norms Committee.**

Case No.	82 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001493AM25
RA File Number	03AX04001447 AM25
Licence No and Date	0311034821/21/06/2024
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant information / documents from the firm:	

Case No.	83 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001494AM25
RA File Number	03AX04001441 AM25
Licence No and Date	0311034822/21/06/2024
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant information / documents from the firm:	

Case No.	84 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001520AM25
RA File Number	03AX04001368 AM25
Licence No and Date	0311034864/24/06/2024

Norms Committee Decision:

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/202425/2 dated 30/04/2024** against advance authorization **No. 0311024276 dated 06/06/2023**, 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.
Carbamazepine Extended-Release Tablets USP 100 mg.(Each tablet contains (i) Carbamazepine 100 mg. (ii) Cellulose Acetate (CA-320S)-Eastman 35.04mg. (iii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)-5.28 mg. Net content (i) 223.220 Kg (ii) 78.216 Kg (iii) 11.786 Kg.)	1 Number	1	Carbamazepine	102.00 mg
		2	Cellulose Acetate (CA 320S) Eastman	29.20 mg
		3	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.
Carbamazepine Extended-Release Tablets USP 200 mg.(Each tablet contains (i) Carbamazepine 200 mg. (ii) Cellulose Acetate (CA-320S)-Eastman 35.04mg. (iii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)-5.28 mg. Net content (i) 467.300 kg (ii) 81.871 Kg (iii)	1 Number	4	Carbamazepine	204.00 mg.
		5	Cellulose Acetate (CA 320S) Eastman	29.20 mg.
		6	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.

12.337 Kg.)				
Carbamazepine Extended-Release Tablets USP 400 mg.(Each tablet contains (i) Carbamazepine 400 mg. (ii) Cellulose Acetate (CA-320S) -Eastman 26.28mg. (iii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 3.96 mg. Net content (i) 223.240 Kg. (ii) 14.667 Kg (iii) 2.210 Kg.)	1 Number	7	Carbamazepine	408.00 mg.
		8	Cellulose Acetate (CA 320S) Eastman	29.20 mg.
		9	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.

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

Case No.	85 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001507AM25
RA File Number	09AX04000202 AM25
Licence No and Date	0911007468/24/06/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	86 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001508AM25
RA File Number	03AX04001364 AM25
Licence No and Date	0311034851/24/06/2024

Norms Committee Decision:

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/Aug/202425/8 dated 28/08/2024** against advance authorization **No. 0311032850 dated 05/04/2024**, 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.
Idezar 300 mg Tablets 28 S (Irbesartan Tablets 300 Mg 28 S)((25,000 Boxes X 28 Tablets per Boxes = 7,00,000 Tablets) (Total Weight of Export Product = 210.000 Kgs) (Net Content weight of Import Product = 226.863 kgs))	1 Number	1	Irbesartan Ph. Eur	306 mg.
Idezar 150 mg Tablets 28 S (Irbesartan Tablets 150 Mg 28 S)((45,525 Boxes X 28 Tablets per Boxes = 12,74,700 Tablets) (Total Weight of Export Product = 191.205 Kgs) (Net Content weight of Import Product = 206.559 kgs))	1 Number	2	Irbesartan Ph. Eur	153 mg.

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

Case No.	87 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001526AM25
RA File Number	03AX04001213 AM25
Licence No and Date	0311034871/25/06/2024
Norms Committee Decision:	
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.
GENTAMICIN EYE/EAR DROPS 5 ML (BACTIGEN EYE/EAR DROPS 5 ML)((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.015 GM NET WT OF BULK DRUG IS 9.390 KGS))	626000 Vial	1	GENTAMICIN SULPHATE	9.578 kg.
GENTAMICIN EYE/EAR DROPS 10 ML (BACTIGEN EYE/EAR DROPS 10 ML)((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.030 GM NET WT OF BULK DRUG IS 0.300 KGS))	10000 Vial	2	GENTAMICIN SULPHATE	0.306 kg.

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

Case No.	88 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001539AM25
RA File Number	07AX04000414 AM25
Licence No and Date	0711011646/25/06/2024

Norms Committee Decision:

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.
----------------	------	---------	--------------	---------------

FERROUS FORTE TABLETS((Each Tab contains 71mg Equivalent to 60mg of Ascorbic Acid and 26mg Equivalent to 24mg of Iron Bisglycinate) (Ascorbic-283.892 KGS) (Iron -550.800 KGS) (No of Tabs-4500000))	834 kg.	1	ASCORBIC ACID DC 97 Percentage SF I.H	283.892 kg.
		2	IRON BISGLYCINATE	550.8 kg.

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

Case No.	89 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	PANACEA BIOTEC PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001565AM25
RA File Number	05AX04000957 AM25
Licence No and Date	0511026325/26/06/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE of Deptt. of Bio-Technology, it was decided to call for following information/documents from the firm:- Copy of received and issued quantity of albumin from the store and its actual consumption with reconciliation duly signed by store manager/head.	

Case No.	90 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001557AM25
RA File Number	08AX04000459 AM25
Licence No and Date	0811011943/26/06/2024
Norms Committee Decision:	

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. 0811010987 dated 12/03/2024**, 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.
ISOSORBIDE MONONITRATE EXTENDED RELEASE TABLETS USP 60 MG(EACH FILM COATED EXTENDED RELEASE TABLETS CONTAINS: DILUTED ISOSORBIDE MONONITRATE (50% DILUTED WITH LACTOSE MONOHYDRATE) USP EQUIVALENT TO ISOSORBIDE MONONITRATE 60MG	1 Number	1	Isosorbide Mononitrate 50 percent Assay. Diluted ISMN (50% diluted with lactose monohydrate) USP	122.40 mg.
ISOSORBIDE MONONITRATE EXTENDED RELEASE TABLETS USP 120 MG(EACH FILM COATED EXTENDED RELEASE TABLETS CONTAINS: DILUTED ISOSORBIDE MONONITRATE (50% DILUTED WITH LACTOSE MONOHYDRATE) USP EQUIVALENT TO ISOSORBIDE MONONITRATE 120MG	1 Number	2	Isosorbide Mononitrate 50 percent Assay. Diluted ISMN (50% diluted with lactose monohydrate) USP	244.80 mg

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

Case No.	91 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024

HQ File Number	HQRNORM APPLY 00001606AM25
RA File Number	03AX04001454 AM25
Licence No and Date	0311034979/27/06/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	92 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001603AM25
RA File Number	05AX04001007 AM25
Licence No and Date	0511026356/27/06/2024

Norms Committee Decision:

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/202223/26 dated 22/03/2024** against advance authorization **No. 0511023881 dated 09/02/2024**, 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.
Atropine Sulfate Ophthalmic Solution USP, 1% 2 ml(Having net content of 3.27 kg of Bulk drug (filling volume 2.32 ml in each number))	1 Number	1	ATROPINE SULPHATE	20.40 mg.
Atropine Sulfate Ophthalmic Solution USP, 1% 5 ml(Having net content of 5.61 kg of Bulk drug (filling volume 5.61 ml in each number))	1 Number	2	ATROPINE SULPHATE	51.00 mg.
Atropine Sulfate Ophthalmic Solution USP, 1% 15 ml(Having net content of 4.77	1 Number	3	ATROPINE SULPHATE	153.0 mg.

kg of Bulk drug (filling volume 15.91 ml in each number))				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	93 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001600AM25
RA File Number	05AX04000773 AM25
Licence No and Date	0511026344/27/06/2024

Norms Committee Decision:

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.
Nepafenac Ophthalmic Suspension, 0.1% w/v NEPALACT Sterile Eye Drops, 5ml((Each ml contains Nepafenac 1.0 mg (Equivalent to 950.000 Gram of Bulk Drug))	190000 Numbers	1	NEPAFENAC (MICRONIZED)	969 gm.
		2	1 LITRE POLYELITE EL POWDER TRANSFER STERILE FULL FLAT FERRULE BAG 4S01ELIR DRAWING NO. SFFB11R HOSOKAWA (EXPO)	Relevant, as per Packing Policy and General Notes.

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

Case No.	94 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001588AM25
RA File Number	31AX04000060 AM25
Licence No and Date	3111003614/27/06/2024

Norms Committee Decision:

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.
DNOVO BP 818 DGE (Tetra Methyl Bisphenol F Diglycidyl Ether)	1 kg.	1	2,6 Xylenol	1.02 kg.
		2	Paraformaldehyde	0.13 kg.
		3	Methanol	0.10 kg.
		4	Epichlorohydrine	0.60 kg.
		5	Sodium Hydroxide	0.228 kg.
		6	Toluene	0.20 kg.
		7	Catalyst (Katalco-71.5)	0.004 kg.

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

Case No.	95 / NC/3/MEET/Dec/202425/12
----------	------------------------------

Case Status	Case Approved
Party Name	UNIMAX LABORATORIES
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001659AM25
RA File Number	05AX04000808 AM25
Licence No and Date	0511026070/01/07/2024

Norms Committee Decision:

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/202223/26 dated 22/03/2024** against advance authorization **No. 0511023881 dated 09/02/2024**, 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.
Azithromycin Tablets 250 mg USP ((Each tablet contains : Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin))	1 Number	1	Azithromycin Dihydrate USP	267.24 mg/Tablet
Azithromycin Tablets 500 mg USP ((Each tablet contains : Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin))	1 Number	2	Azithromycin Dihydrate USP	534.48 mg/Tablet
Azithromycin 250 mg & Lactic Acid Bacillus 60 Million Spores Tablets ((Each tablet contains : Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin and Lactic Acid Bacillus))	1 Number	3	Azithromycin Dihydrate USP	267.24 mg/Tablet
Azithromycin 500 mg & Lactic Acid Bacillus 60 Million Spores Tablets ((Each tablet contains : Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin and Lactic Acid Bacillus))	1 Number	4	Azithromycin Dihydrate USP	534.48 mg/Tablet

Ampicillin Capsules BP, 500 mg (Each Capsules contains Ampicillin BP (As Trihydrate))	1 Number	5	Ampicillin Trihydrate BP	585.282 mg./Capsule
RA concerned may take further necessary action as per above decision of NC.				

Case No.	96 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	BIODEAL PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001661AM25
RA File Number	05AX04000889 AM25
Licence No and Date	0511026379/01/07/2024

Norms Committee Decision:

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 27/09/2024** against advance authorization **No. 0511019975 dated 24/07/2023**, 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.
NASAL SPRAY(MADE FROM 100 MCL SNAP ON PUMP WITH ACTUATOR AND PROTECTION CAP (BONA) BDL SPFN, PROD. CODE CAP045, BONA REF NO. BONA4P20892)	384000 Pieces	1	NASAL ADAPTOR	Relevant on Net to Net basis with accountability
NASAL SPRAY(MADE FROM 50 MCL SNAP ON PUMP WITH ACTUATOR AND PROTECTION CAP (BONA) BDL SPFN, PROD. CODE	192000 Pieces	2	NASAL ADAPTOR	

CAP046, BONA REF NO. BONA4P20892)				
--------------------------------------	--	--	--	--

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

Case No.	97 / NC/3/MEET/Dec/202425/12
Case Status	Case Approved
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001673AM25
RA File Number	03AX04001534 AM25
Licence No and Date	0311035090/01/07/2024

Norms Committee Decision:

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/202324/25** dated **11.03.2024** against advance authorization **No. 0311029148 dated 16.12.2023**, 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.
Isobornyl Cyclohexanol	1 kg.	1	Gum Turpentine Oil	1.582 kg.

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

Case No.	98 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024

HQ File Number	HQRNORM APPLY 00001683AM25
RA File Number	52AX04000062 AM25
Licence No and Date	5211008717/02/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	99 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001694AM25
RA File Number	52AX04000072 AM25
Licence No and Date	5211008732/03/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	100 / NC/3/MEET/Dec/202425/12
Case Status	Case Deferred
Party Name	JUBILANT GENERICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 12 and 10/12/2024
HQ File Number	HQRNORM APPLY 00001713AM25
RA File Number	05AX04001073 AM25
Licence No and Date	0511026456/03/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	