



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/Aug/202425/8

DATED: 28/08/2024

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/Aug/202425/8 dated 28/08/2024 of Norms Committee - III for the year 2024-25 was held on 28/08/2024 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 (HQ)

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00001088AM25
RA File Number	NA
Licence No and Date	NA

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.
FLUOCINONIDE TOPICAL SOLUTION 0.05% 60 ML Tot Wt. 17100 Kgs	1 Number	1	Fluocinonide Micronized USP	30.6 mg
		2	Ethyl Alcohol USP Ethanol 96 %	17.35 gm
		3	DI- Isopropyl Adipate in House	3.99 gm
		4	2 OZ. White HDPE Bottle Drug Oval Plastic Bottle	Relevant as per Packing Policy and Genral Notes
		5	White PP Dropper Tip Cap	Relevant as per Packing Policy and Genral Notes
		6	20 MM Natural LLDPE Dropper Tip 0.020 NEEDLE	Relevant as per Packing Policy and Genral Notes

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

Case No.	2 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00001160AM25
RA File Number	NA
Licence No and Date	NA

Norms Committee Decision:

Decision: The Committee considered the request of firm in details and also discussed report of factory visit. The committee found that in the above mention case export product is in form of Gel not a cream/Ointments and accordingly decided to fix the ad-hoc norms as under :-

Sl. No	Export Product	Quantity
(i)	Medical Creams & Ointments(Testosterone Gel 1.62% 88G Tot Wt. 61600Kgs (Net Wt. Testo 997.92Kgs, Ethyl 45276Kgs, Iso 616Kgs, Carbo 616Kgs, Sodi 246Kgs, Bottle 700000Nos, Cap 700000Nos))	1 Number
(ii)	Creams & Ointments(Testosterone Gel 1%, 788gm Tot Wt. 5280Kgs (Net Wt . Testo 52.80Kgs, Ethyl 3832.22Kgs, Iso 26.4, Carbo 47.52Kgs, Sod 10.03Kgs, Bottle 60000Nos, Cap 60000Nos))	1 Number
(iii)	Medical Creams & Ointments(Testosterone Gel 1%, 5g Sachet Tow Wt. 18000 Kgs (Net Cont Testo 180Kgs, Ethyl 13064.4Kgs, Iso 90Kgs, Carbo 162Kgs, Sod 34.20Kgs))	1 Number
(iv)	Medical Creams & Ointments(Testosterone Gel 1%, 2.5g Sachet Tot Wt. 3450 Kgs (Net Wt. Testo 34.50Kgs, Ethyl 2504.01Kgs, Iso 17.25Kgs, Carbo 31.05Kgs, Sod 6.56Kgs))	1 Number

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

Note: The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	3 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	KRUNAL INDUSTRIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00301989AM22
RA File Number	08AX04000162 AM22
Licence No and Date	0811003592/30/12/2021

Norms Committee Decision:

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

1. **Justificatio for low yield.**
2. **Production/consumption data for the year 2021-2022 duly certified by Auditor of the firm.**

Case No.	4 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred

Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00002548AM23
RA File Number	03AX04002511 AM23
Licence No and Date	0311017048/10/08/2022
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Please get the Advance Authorisation amended to show content of API in export in line with DML.	

Case No.	5 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003366AM23
RA File Number	03AX04003250 AM23
Licence No and Date	0311018155/25/09/2022
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Please get the Advance Authorisation amended to show content of API in export in line with DML.	

Case No.	6 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024

HQ File Number	HQRNORM APPLY 00003417AM23																		
RA File Number	09AX04000478 AM23																		
Licence No and Date	0911003707/27/09/2022																		
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:-																			
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Daptomycin for Injection 350mg/vial (Consist of 52.50 Kgs Daptomycin)</td><td>1 Number</td><td>1</td><td>Daptomycin</td><td>385.0 mg.</td></tr><tr><td>Daptomycin for Injection 500mg/vial (Consist of 150.00Kgs Daptomycin)</td><td>1 Number</td><td>2</td><td>Daptomycin</td><td>550.0 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Daptomycin for Injection 350mg/vial (Consist of 52.50 Kgs Daptomycin)	1 Number	1	Daptomycin	385.0 mg.	Daptomycin for Injection 500mg/vial (Consist of 150.00Kgs Daptomycin)	1 Number	2	Daptomycin	550.0 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Daptomycin for Injection 350mg/vial (Consist of 52.50 Kgs Daptomycin)	1 Number	1	Daptomycin	385.0 mg.															
Daptomycin for Injection 500mg/vial (Consist of 150.00Kgs Daptomycin)	1 Number	2	Daptomycin	550.0 mg.															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	7 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003479AM23
RA File Number	08AX04000835 AM23
Licence No and Date	0811006153/30/09/2022
Norms Committee Decision: Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	8 / NC/3/MEET/Aug/202425/8
Case Status	Case Rejected
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003514AM23
RA File Number	03AX04003421 AM23
Licence No and Date	0311018336/03/10/2022
Norms Committee Decision: Decision: The Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm and it has been observed by the committee that input Galaxmusk Pure (Perfumery Compound) as applied by the firm comes under para 4.11(b) of FTP, 2023, and the said para states that “For export of perfumes, perfumery compounds and various feed ingredients containing vitamins, no authorisation shall be issued by Regional Authority under para 4.07 of HBP and applicants shall be required to apply under para 4.06 of HBP to the Norms Committee”	

Case No.	9 / NC/3/MEET/Aug/202425/8			
Case Status	Case Approved			
Party Name	CIPLA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024			
HQ File Number	HQRNORM APPLY 00003540AM23			
RA File Number	03AX04003155 AM23			
Licence No and Date	0311018363/05/10/2022			
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:-				

			DIOXIDE(SYLOID 244FP)	SION
		4	115CC HDPE BOTTLES 75 ML (250/62.5)	Relevant as per Packing Policy & General Notes.
		5	28-400 WHITE CLIC LOC CAP WITH PRINTED FSM-1	Relevant as per Packing Policy & General Notes.
		6	Cap 28/400 WHT CRC W/FS M-I WITH INDUCTION SEALING	Relevant as per Packing Policy & General Notes.
Amoxicillin and Clavulanate Potassium for Oral Suspension USP 250mg / 62.5mg (Pack Size 100ml)(Each 5ml contains: Amoxycillin Trihydrate USP equivalent to Amoxicillin 250mg, Clavulanate Potassium USP equivalent to Clavulanic Acid 62.50mg)	75000 Numbers	7	Amoxycillin Trihydrate	393.75 kg.
		8	CLAVULANATE POTASSIUM WITH SILICON DIOXIDE 1:1	232.60 kg.
		9	SILICONE DIOXIDE(SYLOID 244FP)	Not covered in SION
		10	115CC HDPE BOTTLES 100 ML (250/62.5)	Relevant as per Packing Policy & General Notes.
		11	28-400 WHITE CLIC LOC CAP WITH PRINTED FSM-1	Relevant as per Packing Policy & General Notes.
		12	Cap 28/400 WHT CRC W/FS M-I WITH	Relevant as per Packing Policy

			INDUCTION SEALING	& General Notes.
Amoxicillin and Clavulanate Potassium for Oral Suspension USP 250mg /62.5mg (Pack Size 150ml)(Each 5ml contains: Amoxycillin Trihydrate USP equivalent to Amoxicillin 250mg, Clavulanate Potassium USP equivalent to Clavulanic Acid 62.50mg)	25000 Numbers	13	Amoxycillin Trihydrate	196.875 kg.
		14	CLAVULANATE POTASSIUM WITH SILICON DIOXIDE 1:1	116.30 kg.
		15	SILICONE DIOXIDE(SYLOID 244FP)	Not covered in SION
		16	115 CC HDPE BOTTLES 150 ML (250/62.5)	Relevant as per Packing Policy & General Notes.
		17	28-400 WHITE CLIC LOC CAP WITH PRINTED FSM-1	Relevant as per Packing Policy & General Notes.
		18	Cap 28/400 WHT CRC W/FS M-I WITH INDUCTION SEALING	Relevant as per Packing Policy & General Notes.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	10 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	CORAL DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003543AM23

RA File Number	05AX04001818 AM23
Licence No and Date	0511015160/06/10/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	11 / NC/3/MEET/Aug/202425/8																			
Case Status	Case Approved																			
Party Name	AETHER INDUSTRIES LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024																			
HQ File Number	HQRNORM APPLY 00003555AM23																			
RA File Number	52AX04001659 AM23																			
Licence No and Date	5211003386/06/10/2022																			
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/202425/5 dated 14/06/2024 against advance authorization No. 5211001047 dated 26/07/2021, 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:-																				
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="4">BIFENTHRIN ALCOHOL</td><td rowspan="4">1 kg.</td><td>1</td><td>2 6 DICHLOROTOLUENE</td><td>1.90 kg.</td></tr><tr><td>2</td><td>TETRAHYDROFURAN</td><td>2.00 kg.</td></tr><tr><td>3</td><td>MAGNESIUM TURNINGS</td><td>0.60 kg.</td></tr><tr><td>4</td><td>n HEPTANE</td><td>1.77 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	BIFENTHRIN ALCOHOL	1 kg.	1	2 6 DICHLOROTOLUENE	1.90 kg.	2	TETRAHYDROFURAN	2.00 kg.	3	MAGNESIUM TURNINGS	0.60 kg.	4	n HEPTANE	1.77 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
BIFENTHRIN ALCOHOL	1 kg.	1	2 6 DICHLOROTOLUENE	1.90 kg.																
		2	TETRAHYDROFURAN	2.00 kg.																
		3	MAGNESIUM TURNINGS	0.60 kg.																
		4	n HEPTANE	1.77 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	12 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003610AM23
RA File Number	34AX04000652 AM23
Licence No and Date	3411002874/10/10/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	13 / NC/3/MEET/Aug/202425/8													
Case Status	Case Approved													
Party Name	ENCEE AROMATICS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024													
HQ File Number	HQRNORM APPLY 00003616AM23													
RA File Number	32AX04000290 AM23													
Licence No and Date	3211003763/11/10/2022													
Norms Committee Decision:														
Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202324/26 dated 22.03.2024 against advance authorization No.3211006285 dated 07.02.2024, 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 rowspan="2">Enamber / Kephalis / Tetrambrone</td><td rowspan="2">1 kg.</td><td>1</td><td>Triethyl Orthoformate</td><td>2.400 kg.</td></tr><tr><td>2</td><td>Mesityl Oxide</td><td>2.700 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Enamber / Kephalis / Tetrambrone	1 kg.	1	Triethyl Orthoformate	2.400 kg.	2	Mesityl Oxide	2.700 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Enamber / Kephalis / Tetrambrone	1 kg.	1	Triethyl Orthoformate	2.400 kg.										
		2	Mesityl Oxide	2.700 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	14 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	LIVEALTH BIOPHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003619AM23
RA File Number	03AX04003335 AM23
Licence No and Date	0311018491/11/10/2022
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Drug Manufacturing Licence (DML) showing approved composition. 2. COA of Import Items. 3. Ratio of 1 kg. Activity and 1 kg. Net with documentary evidence.	

Case No.	15 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003629AM23
RA File Number	34AX04000662 AM23
Licence No and Date	3411002884/11/10/2022
Norms Committee Decision: Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	16 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024																						
HQ File Number	HQRNORM APPLY 00003643AM23																						
RA File Number	09AX04000594 AM23																						
Licence No and Date	0911003780/11/10/2022																						
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:-																							
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="4">Pinaverium Bromide</td> <td rowspan="4">1 kg.</td> <td>1</td> <td>Dihydranopol</td> <td>0.60 kg.</td> </tr> <tr> <td>2</td> <td>2-bromo-4,5-dimethoxy benzyl bromide</td> <td>1.00 kg.</td> </tr> <tr> <td>3</td> <td>Acetone</td> <td>1.00 kg.</td> </tr> <tr> <td>4</td> <td>Toulene</td> <td>0.90 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Pinaverium Bromide	1 kg.	1	Dihydranopol	0.60 kg.	2	2-bromo-4,5-dimethoxy benzyl bromide	1.00 kg.	3	Acetone	1.00 kg.	4	Toulene	0.90 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																			
Pinaverium Bromide	1 kg.	1	Dihydranopol	0.60 kg.																			
		2	2-bromo-4,5-dimethoxy benzyl bromide	1.00 kg.																			
		3	Acetone	1.00 kg.																			
		4	Toulene	0.90 kg.																			
RA concerned may take further necessary action as per above decision of NC.																							

Case No.	17 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003663AM23
RA File Number	09AX04000574 AM23
Licence No and Date	0911003782/12/10/2022
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.
Teriparatide Injection 600 mcg/2.4 ml.((Each MI contains Teriparatide - 250 mcg))	1 Number	1	Teriparatide	660 mcg/injection

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

Case No.	18 / NC/3/MEET/Aug/202425/8
Case Status	Case Withdrawn
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003691AM23
RA File Number	09AX04000567 AM23
Licence No and Date	0911003791/13/10/2022
Norms Committee Decision:	
Decision: The firm vide letter dated 09/06/2023 has informed that they have surrendered their above license to RA. Therefore, the Committee decided to close the application of the firm.	

Case No.	19 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	VINS BIOPRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003701AM23
RA File Number	09AX04000630 AM23
Licence No and Date	0911003795/13/10/2022
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.
Tetanus Antitoxin I.H.S / B.P 1500 IU, Plus [overage of 150 IU in addition] in PFS / vials / Ampoule	100000 Vials	1	Tetanus Antitoxin 2500 IU ml	68 Liter

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

Case No.	20 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ORIENTAL AROMATICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003761AM23
RA File Number	03AX04003660 AM23
Licence No and Date	0311018607/17/10/2022

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.
CAMPHOR USP (AB08005)	1 kg	1	ALPHA PINENE	1.04 kg
		2	Acetic Acid	0.10 kg

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

Case No.	21 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003824AM23
RA File Number	07AX04001015 AM23
Licence No and Date	0711005482/19/10/2022

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.
ATORVASTATIN 10MG TABLETS [904.241 KG])	1 Number	1	ATORVASTATIN CALCIUM TRIHYDRATE	11.059 mg.
		2	D MANNITOL	40.0 mg

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

Case No.	22 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003910AM23
RA File Number	30AX04000299 AM23
Licence No and Date	3011002731/25/10/2022

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.
Injection Urokinase	1000 Vials	1	Urokinase (purified)	1043.46 mg.
		2	Mannitol 0.5%	128.52 gm.
		3	Sodium Chloride (50 mg/vial)	128.52 gm.
		4	Sodium Hydroxide	3.06 gm.

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

Case No.	23 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00003925AM23
RA File Number	09AX04000647 AM23
Licence No and Date	0911003881/27/10/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	24 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	NECTAR LIFE SCIENCES LIMITED
Meeting Number	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024

and Date	
HQ File Number	HQRNORM APPLY 00003987AM23
RA File Number	302404000100 AM20
Licence No and Date	3011002766/01/11/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	25 / NC/3/MEET/Aug/202425/8													
Case Status	Case Approved													
Party Name	SENTISS PHARMA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024													
HQ File Number	HQRNORM APPLY 00004014AM23													
RA File Number	05AX04002182 AM23													
Licence No and Date	0511015566/01/11/2022													
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. 0511019795 dated 18.07.2023, 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>Mydrimax Eye Drops 5 ml. (Tropicamide 0.8%)</td><td>1 Number</td><td>1</td><td>Tropicamide</td><td>40.8 mg / 5ml Vial</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Mydrimax Eye Drops 5 ml. (Tropicamide 0.8%)	1 Number	1	Tropicamide	40.8 mg / 5ml Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Mydrimax Eye Drops 5 ml. (Tropicamide 0.8%)	1 Number	1	Tropicamide	40.8 mg / 5ml Vial										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	26 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000289AM25
RA File Number	NA
Licence No and Date	0511017371/17/02/2023
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Details submitted is for export of Pine Oil not for Terpenyl Acetate. Complete technical details as per Annexure to Appendix-4E.	

Case No.	27 / NC/3/MEET/Aug/202425/8													
Case Status	Case Approved													
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024													
HQ File Number	HQRNORM APPLY 00009143AM24													
RA File Number	09AX04001120 AM24													
Licence No and Date	0911006926/15/03/2024													
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/Jul/202425/7 dated 06.08.2024 against advance authorization No. 0911003379 dated 21.07.2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">(1S,4R)-4-([(2-AMINO-6-CHLORO-5-FORMAMIDO-4- PYRIMIDINYL) AMINO]-2-CYCLOPENTENE-1-METHANOL)</td><td rowspan="2">1 Kg.</td><td>1</td><td>VINCELACTAM</td><td>0.92 kg.</td></tr><tr><td>2</td><td>N 2 AMINO 4 6 DICHLORO 5 PYRIMDINYL</td><td>0.764 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	(1S,4R)-4-([(2-AMINO-6-CHLORO-5-FORMAMIDO-4- PYRIMIDINYL) AMINO]-2-CYCLOPENTENE-1-METHANOL)	1 Kg.	1	VINCELACTAM	0.92 kg.	2	N 2 AMINO 4 6 DICHLORO 5 PYRIMDINYL	0.764 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
(1S,4R)-4-([(2-AMINO-6-CHLORO-5-FORMAMIDO-4- PYRIMIDINYL) AMINO]-2-CYCLOPENTENE-1-METHANOL)	1 Kg.	1	VINCELACTAM	0.92 kg.										
		2	N 2 AMINO 4 6 DICHLORO 5 PYRIMDINYL	0.764 kg										

			FORMAMIDE	
		3	SODIUM BORO HYDRIDE	0.226 kg.
		4	L TARTARIC ACID	0.519 kg.
		5	D TARTARIC ACID	0.76 kg.

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

Case No.	28 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009151AM24
RA File Number	03AX04005709 AM24
Licence No and Date	0311032228/15/03/2024

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. 0311025074 dated 03.07.2023**, 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.
Co-codamol 8/500 tablets (Codeine Phosphate Hemihydrate 8mg and Paracetamol 500mg) (Each Tablet contains Codeine Phosphate Hemihydrate 8mg and Paracetamol 500 mg (Net Wt.Codeine Phosphate Hemihydrate 640.00 KGS))	1 Number	1	Codeine Phosphate Hemihydrate	8.16 mg.

Co-codamol 15/500 tablets (Codeine Phosphate Hemihydrate 15mg and Paracetamol 500mg) (Each Tablet contains Codeine Phosphate Hemihydrate 15mg and Paracetamol 500mg (Net Wt.Codeine Phosphate Hemihydrate 2400.00 KGS))	1 Number	2	Codeine Phosphate Hemihydrate	15.30 mg.
Co-codamol 30/500 tablets (Codeine Phosphate Hemihydrate 30mg and Paracetamol 500mg)(Each Tablet contains Codeine Phosphate Hemihydrate 30mg and Paracetamol 500mg (Net Wt.Codeine Phosphate Hemihydrate 7980.00 KGS))	1 Number	3	Codeine Phosphate Hemihydrate	30.60 mg.

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

Case No.	29 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009169AM24
RA File Number	03AX04005784 AM24
Licence No and Date	0311032244/16/03/2024

Norms Committee Decision:

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

- I. Step wise manufacturing process.
- II. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.
- III. Complete technical details as per Annexure to Appendix 4E for chemical products.
- IV. Stoichiometric balance between import and export on molar basis.
- V. Details of indigenous input with quantity.
- VI. Certificate of Analysis (CoA) of import product.

Case No.	30 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	RECKITT BENCKISER (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009195AM24
RA File Number	05AX04003835 AM24
Licence No and Date	0511024563/18/03/2024

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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DISPRIN REGULAR (ASPIRIN PH.EUR 300MG) ACETYL SALICYLIC ACID 300 mg Tablet (ASPIRIN)	1 Number Tablet	1	SACCHARIN BASE 55Ox	4.50 mg
		2	CALCIUM CARBONATE EP	90.00 mg
DISPRIN EXTRA (ASPIRIN PH.EUR 500MG) ACETYL SALICYLIC ACID 500 mg Tablet (ASPIRIN)	1 Number Tablet	3	SACCHARIN BASE 55Ox	7.50 mg
		4	CALCIUM CARBONATE EP	150.00 mg
DISPRIN DIRECTS/MELTS (ASPIRIN PH.EUR 300MG) ACETYL SALICYLIC ACID 300 mg Tablet (ASPIRIN)	1 Number Tablet	5	SACCHARIN BASE 55Ox	1.00 mg
		6	GLYCINE EP	133.30 mg
DISPRIN CARDIOCARE (ASPIRIN BP 100MG) ACETYL SALICYLIC ACID 100 mg Tablet (ASPIRIN)	1 Number Tablet	7	SACCHARIN BASE 55Ox	0.334 mg

		8	GLYCINE EP	44.40 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	31 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009202AM24
RA File Number	05AX04003994 AM24
Licence No and Date	0511024586/19/03/2024

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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Progesterone Capsules 100mg((Each capsules contains 100 mg of Progesterone) (Equivalent to 300.000 Kg of bulk drug))	3000000 Numbers	1	PROGESTERONE (MICRONIZED)	306 kg
Progesterone Capsules 200mg((Each capsules contains 200 mg of Progesterone) (Equivalent to 600.000 Kg of bulk drug))	3000000 Numbers	2	PROGESTERONE (MICRONIZED)	612 kg
Progesterone Capsules 300mg((Each capsules contains 300 mg of Progesterone) (Equivalent to 900.000 Kg of bulk drug))	3000000Numbers	3	PROGESTERONE (MICRONIZED)	918 kg
Progesterone Capsules 400mg ((Each capsules contains 400 mg of Progesterone) (Equivalent to 1200.000 Kg of bulk drug))	3000000	4	PROGESTERONE	1224 kg

capsules contains 400 mg of Progesterone) (Equivalent to 1200.000 Kg of bulk drug))	Numbers		(MICRONIZED)	
Progesterone Gel 4% w/w((Each Injectable Applicator Gel contain 45mg of Progesterone Gel) (Equivalent to 67.500 Kg of bulk drug))	1500000Numbers	5	PROGESTERONE (MICRONIZED)	74.25 kg
Progesterone Gel 8% w/w((Each Injectable Applicator Gel contain 90mg of Progesterone Gel) (Equivalent to 135.000 Kg of bulk drug) (Pharmaceutical Formulations / Standard Grade) (Equivalent to total 3202.500 Kg of bulk drug))	1500000Numbers	6	PROGESTERONE (MICRONIZED)	148.5 kg

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

Case No.	32 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009206AM24
RA File Number	03AX04005785 AM24
Licence No and Date	0311032328/19/03/2024

Norms Committee Decision:

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

- Step wise manufacturing process.
- Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.
- Complete technical details as per Annexure to Appendix 4E for chemical products.

- iv. Stoichiometric balance between import and export on molar basis.
- v. Details of indigenous input with quantity.
- vi. Certificate of Analysis (CoA) of import product.

Case No.	33 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009209AM24
RA File Number	03AX04005812 AM24
Licence No and Date	0311032330/19/03/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	34 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009219AM24
RA File Number	03AX04005814 AM24
Licence No and Date	0311032351/20/03/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	35 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024

HQ File Number	HQRNORM APPLY 00009247AM24
RA File Number	03AX04005861 AM24
Licence No and Date	0311032405/21/03/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing on next meeting through Video Conference before Norms Committee to explain its case alongwith following clarification / documents from the firm: 1. How the content of import item is more than content of export product, please clarify.	

Case No.	36 / NC/3/MEET/Aug/202425/8										
Case Status	Case Approved										
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024										
HQ File Number	HQRNORM APPLY 00009262AM24										
RA File Number	03AX04005888 AM24										
Licence No and Date	0311032428/21/03/2024										
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. 0311032129 dated 13.03.2024, 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:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>HALQUNOL BP 80</td><td>1 kg.</td><td>1</td><td>8 HYDROXY QUINOLINE</td><td>0.77 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	HALQUNOL BP 80	1 kg.	1	8 HYDROXY QUINOLINE	0.77 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
HALQUNOL BP 80	1 kg.	1	8 HYDROXY QUINOLINE	0.77 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	37 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved

Party Name	MEDREICH LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024													
HQ File Number	HQRNORM APPLY 00009269AM24													
RA File Number	07AX04002026 AM24													
Licence No and Date	0711010859/21/03/2024													
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. 0711008872 dated 02.08.2023, 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">REBAMIPIDE 100 MG TABLETS [5392.157 KG]</td><td rowspan="2">1 Number Tablet</td><td>1</td><td>REBAMIPIDE JP</td><td>102.00 mg</td></tr><tr><td>2</td><td>Ethyl Alcohol 200 Proof</td><td>0.19 ml</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	REBAMIPIDE 100 MG TABLETS [5392.157 KG]	1 Number Tablet	1	REBAMIPIDE JP	102.00 mg	2	Ethyl Alcohol 200 Proof	0.19 ml
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
REBAMIPIDE 100 MG TABLETS [5392.157 KG]	1 Number Tablet	1	REBAMIPIDE JP	102.00 mg										
		2	Ethyl Alcohol 200 Proof	0.19 ml										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	38 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	DCM SHRIRAM INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
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 request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:-	

1. **Reasons for low yield in stage one (48.37%) and stage 2 (85.9%) and yield for third stage have not been given.**
2. **To indicate overall yield of the reaction and value of the by product, if any.**
3. **Stoichiometric Material balance of the reaction.**

Case No.	39 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009277AM24
RA File Number	03AX04005811 AM24
Licence No and Date	0311032452/22/03/2024

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.0311022711 dated 11/04/2023** , 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.
ETHYL ISOBUTYRATE	1 kg.	1	ISOBUTYRIC ACID	0.948 kg

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

Case No.	40 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	AVA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009279AM24

RA File Number	03AX04005818 AM24													
Licence No and Date	0311032462/22/03/2024													
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/Jan/202324/21 dated 24.01.2024 against advance authorization No.0311023611 dated 16.05.2023 , 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>zinc diammonium edta (liquid)- zinc content 9% (? 1)</td><td>1 kg</td><td>1</td><td>ethylenediamine tetra acitic acid</td><td>0.422 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	zinc diammonium edta (liquid)- zinc content 9% (? 1)	1 kg	1	ethylenediamine tetra acitic acid	0.422 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
zinc diammonium edta (liquid)- zinc content 9% (? 1)	1 kg	1	ethylenediamine tetra acitic acid	0.422 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	41 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	GALAXY SURFACTANTS LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009329AM24
RA File Number	03AX04005978 AM24
Licence No and Date	0311032511/26/03/2024
Norms Committee Decision: Decision: The committee considered the case as per agenda and it was decided to fix ad-hoc norms as per SION A-2005 and RA Mumbai is to explain why Advance Authorization is not issued as per SION A-2005.	

Case No.	42 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024

and Date														
HQ File Number	HQRNORM APPLY 00009334AM24													
RA File Number	03AX04005534 AM24													
Licence No and Date	0311032537/26/03/2024													
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.0311031566 dated 28.02.2024, 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 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>Oxcarbazepine USP/BP/EP/IH</td> <td>1 kg.</td> <td>1</td> <td>10-Methoxy Iminostilbene</td> <td>1.10 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Oxcarbazepine USP/BP/EP/IH	1 kg.	1	10-Methoxy Iminostilbene	1.10 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Oxcarbazepine USP/BP/EP/IH	1 kg.	1	10-Methoxy Iminostilbene	1.10 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	43 / NC/3/MEET/Aug/202425/8								
Case Status	Case Approved								
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024								
HQ File Number	HQRNORM APPLY 00009337AM24								
RA File Number	08AX04002293 AM24								
Licence No and Date	0811011114/27/03/2024								
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.0811010634 dated 01.02.2024, 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 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.					

Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)	1 Number	1	Tranexamic acid (Injectable grade, US FDA approved)	1.05 gm/100ml Vial
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RA concerned may take further necessary action as per above decision of NC.

Case No.	44 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009338AM24
RA File Number	08AX04002294 AM24
Licence No and Date	0811011115/27/03/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	45 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009339AM24
RA File Number	08AX04002292 AM24
Licence No and Date	0811011116/27/03/2024
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.0811010634 dated 01.02.2024 , 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.
Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)	1 Number	1	Tranexamic acid (Injectable grade, US FDA approved)	1.05 gm/100ml Vial
RA concerned may take further necessary action as per above decision of NC.				

Case No.	46 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	GALAXY SURFACTANTS LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009343AM24
RA File Number	03AX04006008 AM24
Licence No and Date	0311032549/27/03/2024
Norms Committee Decision:	
Decision: The committee considered the case as per agenda and it was decided to fix ad-hoc norms as per SION A-3574 and RA Mumbai is to explain why Advance Authorization is not issued as per SION A-3574.	

Case No.	47 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009354AM24
RA File Number	03AX04006015 AM24
Licence No and Date	0311032562/27/03/2024
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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BENZYL BROMIDE	1 kg.	1	BENZYL ALCOHOL	0.7015 kg.
		2	HYDROBROMIC ACID 48%	1.12 kg.

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

Case No.	48 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	NIFTY LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009357AM24
RA File Number	09AX04001147 AM24
Licence No and Date	0911006991/27/03/2024

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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
QUETIAPINE FUMARATE (BULK DRUG)	1 kg.	1	Thiophenol	0.554 kg
		2	Hydrazien Hydrate 64%	0.823 kg.
		3	Poly Phosphoric Acid 117%	3.78 kg.

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

Case No.	49 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	ORIENTAL AROMATICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009358AM24
RA File Number	03AX04006024 AM24
Licence No and Date	0311032573/27/03/2024
Norms Committee Decision: Decision: The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm and it has been observed by the committee that input AMBROZANE AB22005 (Perfumery Compound) as applied by the firm comes under para 4.11(b) of FTP, 2023, and the said para states that “For export of perfumes, perfumery compounds and various feed ingredients containing vitamins, no authorisation shall be issued by Regional Authority under para 4.07 of HBP and applicants shall be required to apply under para 4.06 of HBP to the Norms Committee” and also it was decided to call for following information/documents from the firm:- I. Step wise manufacturing process. II. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. III. Complete technical details as per Annexure to Appendix 4E for chemical products. IV. Stoichiometric balance between import and export on molar basis. V. Details of indigenous input with quantity. VI. Certificate of Analysis (CoA) of import product.	

Case No.	50 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	GALAXY SURFACTANTS LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009360AM24

RA File Number	03AX04006006 AM24
Licence No and Date	0311032575/27/03/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Certificate of Analysis (CoA) of export item. 2. Calculation of the requirement raw materials based on chemical reaction and yield of the reaction. 3. Stoichiometric material balance of the reaction.	

Case No.	51 / NC/3/MEET/Aug/202425/8										
Case Status	Case Approved										
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024										
HQ File Number	HQRNORM APPLY 00009370AM24										
RA File Number	05AX04004025 AM24										
Licence No and Date	0511024728/28/03/2024										
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><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Tobramycin Inhalation / Nebuliser Solution 300mg / 5ml((Each ml contains Tobramycin 60mg) (Equivalent to 403.200 Kg of Bulk Drug))</td><td>1344000.0 Numbers</td><td>1</td><td>Tobramycin</td><td>423.36 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Tobramycin Inhalation / Nebuliser Solution 300mg / 5ml((Each ml contains Tobramycin 60mg) (Equivalent to 403.200 Kg of Bulk Drug))	1344000.0 Numbers	1	Tobramycin	423.36 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Tobramycin Inhalation / Nebuliser Solution 300mg / 5ml((Each ml contains Tobramycin 60mg) (Equivalent to 403.200 Kg of Bulk Drug))	1344000.0 Numbers	1	Tobramycin	423.36 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	52 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00009394AM24
RA File Number	03AX04006080 AM24
Licence No and Date	0311032677/31/03/2024

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/202425/5 dated 14.06.2024** against HQ File No.**HQRNORMAPPLY00008586AM24** 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.
SULFADOXINE	1 kg	1	4,6 Dichloro 5-Methoxy Pyrimidine (DCMP)	0.78 kg.
		2	SULFANILAMIDE	0.90 kg.
		3	Diethyl oxalate	Not shown in process.
		4	DIMETHYL FORMAMIDE (DMF)	1.00 kg.

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

Case No.	53 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024

HQ File Number	HQRNORM APPLY 00000009AM25
RA File Number	03AX04006036 AM24
Licence No and Date	0311032713/01/04/2024

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.
Brimonidine Tartrate /Timolol ophthalmic solution 0.2%/0.5% (5 ml Bottle)((Each ml Contains : Brimonidine Tartrate 2mg and Timolol Maleate 6.8 mg equivalent to Timolol 5mg) (Each 5 ml Bottle Contains : Brimonidine Tartrate 10mg and Timolol Maleate 34 mg) - Net wt of Timolol Maleate 6.800 kgs)	1 Number	1	Timolol Maleate	25.50 mg.
		2	BOTTLE	Relevant as per Packing Policy & General Notes.
		3	CAP	Relevant as per Packing Policy & General Notes.
		4	DROPPER	Relevant as per Packing Policy & General Notes.
Brimonidine Tartrate /Timolol ophthalmic solution 0.2%/0.5% (10 ml Bottle)((Each ml Contains : Brimonidine Tartrate 2mg and Timolol Maleate 6.8mg equivalent to Timolol 5mg) (Each 10 ml Bottle Contains :Brimonidine Tartrate 20mg and Timolol Maleate 68 mg) -Net wt of Timolol Maleate 10.200 kgs)	1 Number	5	Timolol Maleate	51.00 mg.
		6	BOTTLE	Relevant as per Packing Policy & General Notes.
		7	CAP	Relevant as per Packing Policy & General Notes.
		8	DROPPER	Relevant as per Packing Policy & General Notes.
Brimonidine Tartrate /Timolol	1 Number	9	Timolol Maleate	76.50 mg.

ophthalmic solution 0.2%/0.5% (15 ml Bottle)(Each ml Contains : Brimonidine Tartrate 2mg and Timolol Maleate 6.8mg equivalent to Timolol 5mg) (Each 15 ml Contains :Brimonidine Tartrate 30mg and Timolol Maleate 102 mg) – Net wt of Timolol Maleate 5.100 kgs)		10	BOTTLE	Relevant as per Packing Policy & General Notes.
		11	CAP	Relevant as per Packing Policy & General Notes.
		12	DROPPER	Relevant as per Packing Policy & General Notes.
Dorzolamide Hydrochloride - Timolol Maleate Ophthalmic Solution USP (5 ml Bottle)((Each ml Contains:Dorzolamide Hydrochloride 22.3mg equivalent to Dorzolamide 20mg and Timolol Maleate 6.8mg equivalent to Timolol 5mg) (Each 5ml Contains: Dorzolamide Hydrochloride 111.50mg &Timolol Maleate 34 mg) Net wt of Timolol Maleate 6.800 kgs)	1 Number	13	Timolol Maleate	25.50 mg.
		14	BOTTLE	Relevant as per Packing Policy & General Notes.
		15	CAP	Relevant as per Packing Policy & General Notes.
		16	DROPPER	Relevant as per Packing Policy & General Notes.
Dorzolamide Hydrochloride - Timolol Maleate Ophthalmic Solution USP (10 ml Bottle)((Each ml Contain: Dorzolamide Hydrochloride 22.3mg equivalent to Dorzolamide 20mg and Timolol Maleate 6.8mg equivalent to Timolol 5mg) (Each 10ml Contains: Dorzolamide Hydrochloride 223 mg &Timolol Maleate 68 mg) Net wt of Timolol Maleate 6.800 kgs)	1 Number	17	Timolol Maleate	51.00 mg.
		18	BOTTLE	Relevant as per Packing Policy & General Notes.
		19	CAP	Relevant as per Packing Policy & General Notes.
		20	DROPPER	Relevant as per Packing Policy & General Notes.

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

Case No.	54 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000010AM25
RA File Number	09AX04001031 AM24
Licence No and Date	0911007011/01/04/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Jan/202324/21 dated 24.01.2024** against advance Authorization No. **0911006353 dated 11.12.2023** 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.
RIFAXIMIN(Ph. Eur)	1 kg.	1	4-O-Carboxymethyl-1-Deoxy-1,4-Dihydro-4-Hydroxy-1-Oxorifamycin-γ-Lactone	1.50 kg.

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

Case No.	55 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000011AM25
RA File Number	09AX04001077 AM24
Licence No and Date	0911007013/01/04/2024

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/202324/11 dated 22.08.2023** against advance Authorization No. **0911003559 dated 30.08.2022** it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Empagliflozin-IH	1 kg.	1	(1S)-1,5-Anhydro-1-(4-Chloro-3-{4-[(3S)- Tetra hydrofuran-3-yloxy]Benzyl}Phenyl)-D-Glucitol	1.30 kg.

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

Case No.	56 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000028AM25
RA File Number	30AX04000590 AM24
Licence No and Date	3011005003/02/04/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	57 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000043AM25
RA File Number	03AX04006083 AM24
Licence No and Date	0311032759/02/04/2024
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. **0311023981** dated **26.05.2023** it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
LUMEFANTRINE	1 kg.	1	FLUORENE	0.90 kg.
		2	DIMETHYL FORMAMIDE (DMF)	0.50 kg.
		3	DI N BUTYLAMINE (N-DBA)	0.060 kg.
		4	4-CHLOROBENZALDEHYDE	0.3476 kg.
		5	SODIUM BOROHYDRIDE	0.555 kg.

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

Case No.	58 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000050AM25
RA File Number	08AX04000003 AM25
Licence No and Date	0811011199/02/04/2024

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.
Phenylephrine Hydrochloride Injection USP, 10 mg/mL (5 mL)	1 Number	1	Phenylephrine HCl USP/Ph.Eur	55 mg / Vial
Phenylephrine Hydrochloride Injection USP, 10 mg/mL(10 mL)	1 Number	2	Phenylephrine HCl USP/Ph.Eur	110 mg / Vial

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

Case No.	59 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000061AM25
RA File Number	05AX04004115 AM24
Licence No and Date	0511024832/03/04/2024

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.
Fluorometholone Acetate 0.1% & Tobramycin 0.3% ophthalmic suspension - 5ml (Each ml contains 3 mg of Tobramycin)	1 Number	1	Tobramycin USP IP	15.75 mg

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

Case No.	60 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000065AM25
RA File Number	09AX04001116 AM24
Licence No and Date	0911007027/03/04/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	61 / NC/3/MEET/Aug/202425/8			
Case Status	Case Approved			
Party Name	OPTIMUS DRUGS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024			
HQ File Number	HQRNORM APPLY 00000066AM25			
RA File Number	09AX04001075 AM24			
Licence No and Date	0911007031/03/04/2024			
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/202324/11 dated 22.08.2023 against advance Authorization No. 0911003559 dated 30.08.2022 it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Empagliflozin-IH	1 kg.	1	(3R,4S,5S,6R)-2-(4-Chloro-3-(4-(((S)-Tetra hydro furan-3-yl)oxy) Benzyl) Phenyl)-6-(Hydroxyl Methyl)-2-Methoxytetra	1.525 kg.

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

Case No.	62 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	PLASTIBLENDS INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000067AM25
RA File Number	03AX04006127 AM24
Licence No and Date	0311032797/03/04/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Please explain the use of BOPP (which is a film) in manufacturing of Additive Masterbatch.	

Case No.	63 / NC/3/MEET/Aug/202425/8	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024	
HQ File Number	HQRNORM APPLY 00000076AM25	
RA File Number	03AX04006163 AM24	
Licence No and Date	0311032812/04/04/2024	
Norms Committee Decision:		
Decision: The Committee considered the request of firm in details and also discussed report of factory visit. The committee found that in the above mention case export product is in form of Gel not a cream/Ointments and accordingly decided to fix the ad-hoc norms as under :-		
Sl. No.	Export Product	Quantity

1	Medical Creams and Ointments(ADAPALENE GEL 0.3% 45GM Tube Wt: 7499.97 Kgs (Net Cont: Adapal22.50Kgs, Edetate7.50Kgs, Poloxamer15Kgs, Carbomer82.5Kgs, Methy15Kgs, Propel300Kgs, sodium Hy 26.25Kgs,Hydrocl37.50Kgs,Tubes166666Nos))	1 Number
2	Medical Creams and Ointments(ADAPALENE GEL 0.3% 45GM Pump Wt: 750.06Kgs (Net Cont: Adapal2.25Kgs, Edetate0.75Kgs, Poloxamer1.50Kgs, Carbomer8.25Kgs, Methyl1.50Kgs, Propel30Kgs, sodium Hy 2.63Kgs, Hydrocl3.75Kgs,Pump body16668Nos Pump Engine 16668Nos))	1 Number

Sl. No.	Import Items	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy & Genral Notes.

Note: The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	64 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000084AM25
RA File Number	08AX04002289 AM24
Licence No and Date	0811011217/04/04/2024
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.
TRETINOIN CREAM USP 0.1% 20 GRAM (EACH GRAM CONTAIN 1.10 MG OF TRETINOIN USP) ((NET CONTENT OF ACTIVE INGREDIENT : TRETINOIN USP - 11121.000 GRAMS))	505500 Numbers	1	TRETINOIN USP	10312.20 gm.
		2	ALUMINIUM TUBES FOR TRETINOIN CREAM USP 0.1% 20 GRAM	Relevant as per Packing Policy and Genral Notes
TRETINOIN CREAM USP 0.1% 45 GRAM (EACH GRAM CONTAIN 1.10 MG OF TRETINOIN USP)((NET CONTENT OF ACTIVE INGREDIENT : TRETINOIN USP - 31630.500 GRAMS))	639000 Numbers	3	TRETINOIN USP	29330.10 gm.
		4	ALUMINIUM TUBES FOR TRETINOIN CREAM USP 0.1% 45 GRAM	Relevant as per Packing Policy and Genral Notes

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

Case No.	65 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000093AM25
RA File Number	08AX04002290 AM24
Licence No and Date	0811011225/04/04/2024
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. **0811009842** dated **02.11.2023** 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.
Metamizole Sodium, Pitofenone Hydrochloride & Fenpiverinium Bromide Tablets. (Spasmalin Tablets 500mg). (Each coated tablet contains 500 MG of Metamizole Sodium B P mg Excipients...as per q.s.	25000000 Numbers	1	Metamizole Sodium B. P.	12750 kg.
Metamizole Sodium, Pitofenone Hydrochloride & Fenpiverinium Bromide Tablets. (Spasmalin Tablets 500mg). (Each coated tablet contains 500 MG of Metamizole Sodium B P mg Excipients...as per q.s.	13635000 Numbers	2	Metamizole Sodium B. P.	6953.85 kg.

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

Case No.	66 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000095AM25
RA File Number	08AX04002339 AM24
Licence No and Date	0811011226/04/04/2024
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. **0811009102 dated 16.08.2023** 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.
Opipramol Dihydrochloride Tablets 50 MG (OPIPRAMOL HEUMANN 50 MG) (Each film coated tablet contains: Opipramol Dihydrochloride 50 mg Excipients q.s.	1 Number	1	Opipramol Dihydrochloride	51 mg/Tablet
Opipramol Dihydrochloride Tablets 100 MG (OPIPRAMOL HEUMANN 100 MG) (Each film coated tablet contains: Opipramol Dihydrochloride 100 mg Excipients.q.s.	1 Number	2	Opipramol Dihydrochloride	102mg/Tablet

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

Case No.	67 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000096AM25
RA File Number	08AX04000006 AM25
Licence No and Date	0811011227/04/04/2024
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. **0811008977** dated **01.08.2023** 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.
CANDESARTAN CILEXETIL 2 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 2 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 0.180 KG IN EXPORT ITEM)	1 Number	1	CANDESARTAN CILEXETIL PH.EUR	2.04 mg
CANDESARTAN CILEXETIL 4 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 4 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 1.440 KG IN EXPORT ITEM)	1 Number	2	CANDESARTAN CILEXETIL PH.EUR	4.08 mg
CANDESARTAN CILEXETIL 8 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 8 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 5.760 KG IN EXPORT ITEM)	1 Number	3	CANDESARTAN CILEXETIL PH.EUR	8.16 mg
CANDESARTAN CILEXETIL 16 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 16 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 399.226	1 Number	4	CANDESARTAN CILEXETIL PH.EUR	16.32 mg

KG IN EXPORT ITEM)				
CANDESARTAN CILEXETIL 32 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 32 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 14.400 KG IN EXPORT ITEM)	1 Number	5	CANDESARTAN CILEXETIL PH.EUR	32.64 mg
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZID E TABLETS 8 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 8 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 2.520 KG IN EXPORT ITEM)	1 Number	6	CANDESARTAN CILEXETIL PH.EUR	8.16 mg
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZID E TABLETS 16 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 16 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 46.800 KG IN EXPORT ITEM)	1 Number	7	CANDESARTAN CILEXETIL PH.EUR	16.32 mg
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZID E TABLETS 32 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF	1 Number	8	CANDESARTAN CILEXETIL PH.EUR	32.64 mg

CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 11.520 KG IN EXPORT ITEM)				
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZID E TABLETS 32 MG +25 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH EUR. 25 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 11.520 KG IN EXPORT ITEM)	1 Number	9	CANDESARTAN CILEXETIL PH.EUR	32.64 mg

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

Case No.	68 / NC/3/MEET/Aug/202425/8		
Case Status	Case Approved		
Party Name	ENCUBE ETHICALS PRIVATE LIMITED		
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024		
HQ File Number	HQRNORM APPLY 00000101AM25		
RA File Number	03AX04006141 AM24		
Licence No and Date	0311032832/05/04/2024		
Norms Committee Decision:			
Decision: The Committee considered the request of firm in details and also discussed report of factory visit. The committee found that in the above mention case export product is in form of Gel not a cream/Ointments and accordingly decided to fix the ad-hoc norms as under :-			
Sl. No.	Export Product		Quantity
1	MEDICAL CREAM AND OINTMENT(Testosterone Gel 1%,88gm Pump Pack Tot Wt 5280Kg (Net Cont. TestosteroneUSP-52.80 kg, Ethanol 96% -		1 Number

	3832.22kg,IsopropylMyristateNF-26.40kg,Carbopol980 NF -47.52kg, Sodium Hydroxide NF- 10.03kg,WHITE COLORS OF BAG BOTTLE 112mL-60000nos, SP943+PUMP 60000nos))	
2	MEDICAL CREAM AND OINTMENT(Testosterone Gel 1%, 5g Sachet Tot Wt 7350Kg(Testosterone USP-73.5kg,Ethanol 96 %-5334.63kg,Isopropyl Myristate NF - 36.75kg,Carbopol 980 NF-66.15kg,Sodium Hydroxide NF-13.97kg))	1 Number
3	MEDICAL CREAM AND OINTMENT(Testosterone Gel 1%, 2.5g Sachet Tot Wt 1425Kg(Testosterone USP14.25kg, Ethanol 96 %- 1034.27 kg, Isopropyl Myristate NF- 7.13kg,Carbopol 980 NF-12.83kg, Sodium Hydroxide NF 2.71kg))	1 Number

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

Note: The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	69 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000102AM25
RA File Number	03AX04006162 AM24
Licence No and Date	0311032839/05/04/2024

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:-

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Fluocinolone Acetonide Topical Solution USP 0.01 % (60 ML) Tot Wt: 24000Kgs (Net Cont: Fluocinolone 2.40Kgs, 2 Oz. White HDPE 400000Nos, White PP dropper 400000Nos, 20MM Natural LLDPE 400000Nos))	1 Number

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

Note: The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	70 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	LIVMORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000105AM25
RA File Number	34AX04000777 AM24
Licence No and	3411004764/05/04/2024

Date	
Norms Committee Decision: Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete chemical description of import item with CoA from Foreign Supplier.	

Case No.	71 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	LIVMORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000106AM25
RA File Number	34AX04000776 AM24
Licence No and Date	3411004765/05/04/2024
Norms Committee Decision: Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete chemical description of import item with CoA from Foreign Supplier.	

Case No.	72 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000108AM25
RA File Number	03AX04000029 AM25
Licence No and Date	0311032850/05/04/2024
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.
Idezar 150 mg Tablets 28 S (Irbesartan Tablets 150 Mg 28 S)((15,175 Boxes X 28 Tablets per Boxes = 4,24,900 Tablets) (Total Weight of Export Product = 63.735 Kgs)	1 Number	1	Irbesartan Ph. Eur.	153 mg
Idezar 300 mg Tablets 28 S (Irbesartan Tablets 300 Mg 28 S)((37,800 Boxes X 28 Tablets per Boxes = 10,58,400 Tablets) (Total Weight of Export Product = 317.520 Kgs)	1 Number	2	Irbesartan Ph. Eur.	306 mg

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

Case No.	73 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000145AM25
RA File Number	03AX04000009 AM25
Licence No and Date	0311032889/08/04/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	74 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024

and Date	
HQ File Number	HQRNORM APPLY 00000155AM25
RA File Number	08AX04000014 AM25
Licence No and Date	0811011244/08/04/2024

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.
PIPERACILLIN TAZOBACTAM 4.5gm (PIPERACILLIN AND TAZOBACTAM FOR INJECTION USP 4.5 GM))	1 Number Vial	1	Piperacillin Sodium and Tazobactam Sodium for Injection (8:1) (Bulk Sterile Mixture) USP	4.80 gm/ Vial

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

Case No.	75 / NC/3/MEET/Aug/202425/8		
Case Status	Case Approved		
Party Name	ENCUBE ETHICALS PRIVATE LIMITED		
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024		
HQ File Number	HQRNORM APPLY 00000171AM25		
RA File Number	03AX04006114 AM24		
Licence No and Date	0311032906/10/04/2024		

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:-

Sl. No.	Export Product	Quantity
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1	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 10 Gm tube Tot Wt. 8775 Kgs (Net Cont: Clotri 87.75Kgs, Octy 1184.63Kgs,Cetyl 263.25Kgs,Ceto 877.50Kgs, Emp tubes 877500Nos))	1 Number
2	Medical Creams & Ointments(Clotrimazole 1 Percentage Vaginal cream 35Gm Tube with 6 Applicator Tot Wt. 6999.65Kgs (Net Cont. Clotri 70Kgs, Octy 944.95Kgs,Cetyl 209.99Kgs, Ceto 699.97Kgs, Emp tubes 199990Nos, Appli 1199940 Nos))	1 Number
3	Medical Creams & Ointments(Clotrimazole1 Percentage Cream 100 Gm Tube Tot Wt. 3000Kgs (Net Cont: Clotri 30Kgs, Octy 405Kgs,Cetyl 90Kgs,Ceto 300Kgs, Emp tubes 30000Nos))	1 Number
4	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 20Gm.Tube Tot Wt. 39200Kgs (Net Cont: Clotri 392Kgs, Octy 5292Kgs,Cetyl 1176Kgs,Ceto 3920Kgs, Emp tubes 1960000Nos))	1 Number
5	Medical Creams & Ointments(Clotrimazole 1 PercentageCream 50 Gm-Tube Tot Wt. 21700Kgs (Net Cont: Clotri 217Kgs, Octy 2929.50Kgs,Cetyl 651Kgs,Ceto 2170Kgs, Emp tubes 434000Nos))	1 Number
6	Medical Creams & Ointments(Clotrimazole 2 Percentage Vaginal Cream 20 Gm.Tube with 3 Applicator Tot Wt. 4000Kgs (Net Cont. Clotri 80Kgs, Octy 540Kgs,Cetyl 120Kgs, Ceto 400Kgs, Emp tubes 200000Nos, Appli 600000Nos))	1 Number
7	Medical Creams & Ointments(Clotrimazole10 PercentageVaginal cream 5 Gm Tube with 1 Applicator Tot Wt. 100Kgs (Net Cont. Clotri 10Kgs,Cetyl 3Kgs, Ceto 3.5Kgs, Emp tubes 20000Nos, Appli 20000Nos))	1 Number
8	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 5 Gm Tube Tot Wt. 2125Kgs (Net Cont: Clotri 21.25Kgs, Octy 286.88Kgs,Cetyl 63.75Kgs,Ceto 212.50Kgs, Emp tubes 425000Nos)	1 Number
9	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 3 Gm. Tube Tot Wt. 1800Kgs (Net Cont: Clotri 18Kgs, Octy 243Kgs,Cetyl 54Kgs,Ceto 180Kgs, Emp tubes 600000Nos)	1 Number
10	Medical Creams & Ointments(Clotrimazole 1 Percentage cream 10 Gm. Tube with Fluconazole Capsule Tot Wt. 1140Kgs (Net Cont: Clotri 11.40 Kgs, Octy 153.90 Kgs,Cetyl 34.20 Kgs,Ceto 114Kgs, Emp tubes 114000Nos)	1 Number

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

Note: The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	76 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000186AM25
RA File Number	05AX04000033 AM25
Licence No and Date	0511024949/10/04/2024

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. **0511024319 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.
Meropenem Sodium Sterile	1 kg.	1	Meropenem Trihydrate	0.8968 kg.

((Meropenem for Injection))			(Non Sterile)	
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RA concerned may take further necessary action as per above decision of NC.

Case No.	77 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000189AM25
RA File Number	34AX04000916 AM24
Licence No and Date	3411004788/10/04/2024

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.
Anticancer drugs – Other (Fluorouracil Injection USP 2.5 gm 50 ML)	60000 Numbers	1	Fluorouracil USP	156.0 kg.
Anticancer drugs – Other (Fluorouracil Injection USP 5 gm 100 ML)	45000 Numbers	2	Fluorouracil USP	225.0 kg.

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

Case No.	78 / NC/3/MEET/Aug/202425/8
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Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000191AM25
RA File Number	05AX04000086 AM25
Licence No and Date	0511024958/10/04/2024

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. **0511023326 dated 17.01.2024** it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Moxifloxacin HCL and Dexamethasone Sodium Phosphate Eye Drops 0.5%w/v, 0.1% w/v, 5ml((Each ml contain Moxifloxacin Base 5mg. equi. to Moxifloxacin HCL 5.45mg. & Dexamethasone Phosphate 1mg equi. to Dexamethasone Sodium Phosphate 1.1mg (Equi.to 981.000gm Moxifloxacin HCL and 198.000gm Dexamethasone Sodium Phosphate Bulk Drug))	36000 Numbers	1	Moxifloxacin Hydrochloride	1030.04 gm.
		2	Dexamethasone Sodium Phosphate	207.90 gm.

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

Case No.	79 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	STERLING SPECIALITY CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000209AM25
RA File Number	03AX04000077 AM25

Licence No and Date	0311032963/12/04/2024			
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. 0311027082 dated 13/09/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2-Ethylhexyl Thioglycolate (EHTG)	1 kg.	1	2-ETHYL HEXANOL	0.684 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	80 / NC/3/MEET/Aug/202425/8			
Case Status	Case Approved			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024			
HQ File Number	HQRNORM APPLY 00000213AM25			
RA File Number	07AX04002122 AM24			
Licence No and Date	0711011047/12/04/2024			
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/202324/11 dated 22.08.2023 against advance authorization No. 0711005078 dated 23.08.2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PREMIX OF NIFUROXAZIDE (Each gm of Premix contains Nifuroxazide 0.552 gm)	12600 kg.	1	NIFUROXAZIDE BP/EP	7024.752 kg.

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

Case No.	81 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000215AM25
RA File Number	07AX04000009 AM25
Licence No and Date	0711011049/12/04/2024

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. 0711010708 dated 07.03.2024**, 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.
DIRECT COMPRESSION GRANULES OF PHLOROGLUCINOL 160MG ODT PREMIX(DIRECT COMPRESSION GRANULES OF PHLOROGLUCINOL 160MG ODT PREMIX (Each 450mg Premix Contains 160mg Phloroglucinol) contents 625.778kgs)	1 kg.	1	PHLOROGLUCINOL DIHYDRATE Ph.Eur	0.359 kg.

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

Case No.	82 / NC/3/MEET/Aug/202425/8																		
Case Status	Case Approved																		
Party Name	PIRAMAL PHARMA LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024																		
HQ File Number	HQRNORM APPLY 00000234AM25																		
RA File Number	03AX04000127 AM25																		
Licence No and Date	0311033003/15/04/2024																		
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><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Vibegron (Gemtesa)Tablets 75 mg</td><td>1 Number</td><td>1</td><td>Vibegron</td><td>76.50 mg/ Tablet</td></tr><tr><td>Vibegron (Gemtesa)Tablets 75 mg</td><td>1 Number</td><td>2</td><td>Vibegron</td><td>76.50 mg/ Tablet</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Vibegron (Gemtesa)Tablets 75 mg	1 Number	1	Vibegron	76.50 mg/ Tablet	Vibegron (Gemtesa)Tablets 75 mg	1 Number	2	Vibegron	76.50 mg/ Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Vibegron (Gemtesa)Tablets 75 mg	1 Number	1	Vibegron	76.50 mg/ Tablet															
Vibegron (Gemtesa)Tablets 75 mg	1 Number	2	Vibegron	76.50 mg/ Tablet															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	83 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000260AM25
RA File Number	03AX04000132 AM25
Licence No and Date	0311033059/16/04/2024
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.
Flormax 20% / Florfenicol Oral Solution 200mg/ml((Pack size 1000ML), Each ml contains: Florfenicol 200mg,	1 Number	1	Florfenicol	0.204 kg

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

Case No.	84 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000262AM25
RA File Number	03AX04000157 AM25
Licence No and Date	0311033083/16/04/2024

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.
3, 4 - Dichloro Phenyl Acetic Acid	1 kg.	1	3, 4 - Dichloro toluene (3,4-DCT)	1.047 kg.
		2	Sodium Cyanide	0.2812 kg.
		3	Sodium Hydroxide Flakes	0.2886 kg.

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

Case No.	85 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ENALTEC LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000263AM25
RA File Number	03AX04000180 AM25
Licence No and Date	0311033084/16/04/2024

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. 0311031566 dated 28.02.2024**, 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.
Oxcarbazepine USP	1 kg.	1	10-Methoxy Iminostilbene	1.10 kg.

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

Case No.	86 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000268AM25
RA File Number	09AX04001014 AM24
Licence No and Date	0911007079/16/04/2024

Norms Committee Decision:

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

Master batch formula (MBF) showing net content of import item in export.

Case No.	87 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	INDIA GLYCOLS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000272AM25
RA File Number	05AX04000114 AM25
Licence No and Date	0511025004/16/04/2024

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/202122/7 dated 13.08.2021** against advance authorization No. **0510408634 dated 26.11.2018**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Mono Ethylene Glycol (MEG)	1 Kg	1	Denatured Ethyl Alcohol	1.123 kg
		2	Silver Catalyst (Activity 29-30%)	0.000284 kg
		3	Alumina Catalyst	0.000362 kg

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

Case No.	88 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000276AM25
RA File Number	03AX04000156 AM25
Licence No and Date	0311033116/16/04/2024

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 as the export item is a solution:-

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Clobetasol Propionate Topical Solution USP, 0.05%, 25ml Tot Wt: 2700Kgs (Net Cont: Clobetasol Propionate USP 1.35Kgs, LDPE Dropper tip FOR OVAL BOTTLE 108000Nos))	1 Number
2	Medical Creams & Ointments(Clobetasol Propionate Topical Solution USP, 0.05%, 50ml Tot Wt: 17400Kgs (Net Cont: Clobetasol Propionate USP 8.7Kgs, LDPE Dropper tip FOR OVAL BOTTLE 348000Nos))	1 Number

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

Note: The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

Case No.	89 / NC/3/MEET/Aug/202425/8			
Case Status	Case Approved			
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024			
HQ File Number	HQRNORM APPLY 00000277AM25			
RA File Number	03AX04000189 AM25			
Licence No and Date	0311033115/16/04/2024			
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:-				
</				

Case No.	90 / NC/3/MEET/Aug/202425/8			
Case Status	Case Approved			
Party Name	SENTISS PHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024			
HQ File Number	HQRNORM APPLY 00000299AM25			
RA File Number	05AX04004117 AM24			
Licence No and Date	0511024955/18/04/2024			

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. 0511023621 dated 02.02.2024**, 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.
Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml (Each ml contains 10 mg of Brinzolami	1 Vial	1	Brinzolamide Micronized Sterile	51.00 mg/ Vial

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

Case No.	91 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000301AM25
RA File Number	09AX04000017 AM25
Licence No and Date	0911007083/18/04/2024

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.
METOPROLOL SUCCINATE	1 kg.	1	4 2 Methoxyethylphenol	0.694 kg.
		2	Epichloro Hydrine	0.6179 kg.

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

Case No.	92 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000306AM25
RA File Number	08AX04000057 AM25
Licence No and Date	0811011317/18/04/2024

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/Dec/202324/19 dated 05.01.2024** against advance authorization **No. 3411003310 dated 28.01.2023**, 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.
MINOXIDIL TOPICAL AEROSOL 5% (FOAM) 60 Gm CAN (MINOXIDIL TOPICAL AEROSOL 5% (FOAM) 60 Gm CAN	1 Number	1	MINOXIDIL USP	3.06 gm.

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

Case No.	93 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000312AM25

RA File Number	05AX04000176 AM25													
Licence No and Date	0511025034/18/04/2024													
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> <tr> <td>Formoterol Fumarate Inhalation Solution 20 mcg/2 mL (0.02 mg/2 mL),(Having net content of 92.25 gm of Bulk drug (filling volume 2.25 ml in each number))</td> <td>4100000.0 Numbers</td> <td>1</td> <td>FORMOTEROL FUMARATE DIHYDRATE USP</td> <td>86.10 gm.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Formoterol Fumarate Inhalation Solution 20 mcg/2 mL (0.02 mg/2 mL),(Having net content of 92.25 gm of Bulk drug (filling volume 2.25 ml in each number))	4100000.0 Numbers	1	FORMOTEROL FUMARATE DIHYDRATE USP	86.10 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Formoterol Fumarate Inhalation Solution 20 mcg/2 mL (0.02 mg/2 mL),(Having net content of 92.25 gm of Bulk drug (filling volume 2.25 ml in each number))	4100000.0 Numbers	1	FORMOTEROL FUMARATE DIHYDRATE USP	86.10 gm.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	94 / NC/3/MEET/Aug/202425/8								
Case Status	Case Approved								
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024								
HQ File Number	HQRNORM APPLY 00000326AM25								
RA File Number	05AX04000127 AM25								
Licence No and Date	0511025055/19/04/2024								
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. 0511018638 dated 04.05.2023, 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> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					

Dorzolamide and Timolol Ophthalmic Solution, 2.0%w/v + 0.5%w/v, 5ml Sterile Eye Drops((Each ml contains Dorzolamide Hydrochloride equivalent to Dorzolamide 20 mg (Equivalent to 12.000Kg of Bulk Drug), and Timolol Maleate equivalent to Timolol 5.0 mg (Equivalent to 3.000 Kg. of Bulk Drug))	120000 Numbers	1	DORZOLAMIDE HYDROCHLORIDE	14.051 kg.
		2	TIMOLOL MALEATE	4.284 kg.

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

Case No.	95 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	SYNERGIA SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000333AM25
RA File Number	03AX04000023 AM25
Licence No and Date	0311033222/19/04/2024
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 from the firm:	

Case No.	96 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	VINCIT LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000334AM25
RA File Number	05AX04004078 AM24
Licence No and	0511025080/19/04/2024

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

Case No.	97 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000348AM25
RA File Number	03AX04000076 AM25
Licence No and Date	0311033249/22/04/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	98 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000349AM25
RA File Number	03AX04000120 AM25
Licence No and Date	0311033250/22/04/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	99 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024

HQ File Number	HQRNORM APPLY 00000355AM25													
RA File Number	03AX04000287 AM25													
Licence No and Date	0311033255/22/04/2024													
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. 0311029157 dated 06.12.2023, 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>AZITHROMYCIN DIHYDRATE</td><td>1 kg.</td><td>1</td><td>AZITHROMYCIN AMINE</td><td>0.9434 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	AZITHROMYCIN DIHYDRATE	1 kg.	1	AZITHROMYCIN AMINE	0.9434 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
AZITHROMYCIN DIHYDRATE	1 kg.	1	AZITHROMYCIN AMINE	0.9434 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	100 / NC/3/MEET/Aug/202425/8													
Case Status	Case Approved													
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024													
HQ File Number	HQRNORM APPLY 00000372AM25													
RA File Number	03AX04006123 AM24													
Licence No and Date	0311033283/23/04/2024													
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/202324/16 dated 17.11.2023 against advance authorization No. 0311024400 dated 09.06.2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Fenofibrate Bulk Granulate</td><td>1 kg.</td><td>1</td><td>Fenofibrate Micronized IH/Ph.Eur</td><td>0.3155 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Fenofibrate Bulk Granulate	1 kg.	1	Fenofibrate Micronized IH/Ph.Eur	0.3155 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Fenofibrate Bulk Granulate	1 kg.	1	Fenofibrate Micronized IH/Ph.Eur	0.3155 kg.										

		2	Hypromellose (2910, 3 cps) Ph. Eur	0.0625 kg.
		3	Docusate Sodium Ph.Eur	0.0062 kg.
		4	Sucrose Ph.Eur	0.3124 kg.
		5	Sodium Lauril Sulfate Ph.Eur	0.0216 kg.
		6	Lactose Monohydrate Ph.Eur	0.2804 kg.

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

Case No.	101 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000386AM25
RA File Number	05AX04000226 AM25
Licence No and Date	0511025124/23/04/2024

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.
PROPARACAINE HYDROCHLORIDE OPHTHALMIC SOLUTION USP 0.5%,15ML(HAVING NET CONTENT OF 25.47 KG OF PROPARACAINE HYDROCHLORIDE USP)	320000.0 Numbers	1	PROPARACAINE HYDROCHLORIDE USP	24.48 kg.

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

Case No.	102 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000387AM25
RA File Number	08AX04000059 AM25
Licence No and Date	0811011334/23/04/2024

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/202425/5 dated 14.06.2024** against advance authorization **No. 3410046549 dated 13.11.2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% - 15 gm Tube(Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% - 15 gm Tube net content of active ingredients 6.136 kgs.)	1 Number	1	Nystatin USP	238.65 mg.
Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% - 30 gm tube(Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% - 30 gm tube net content of active ingredients 12.273 kgs.)	1 Number	2	Nystatin USP	477.30 mg.
Nystatin and Triamcinolone Acetonide	1 Number	3	Nystatin USP	954.61 mg.

Ointment USP, 1,00,000 UNITS / GM; 0.1% - 60 gm(Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% - 60 gm tube net content of active ingredients 25.545 kgs.)				
Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% - 15 gm tube(Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% - 15 gm tube net content of active ingredients 6.818 kgs.)	1 Number	4	Nystatin USP	238.65 mg
Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% - 30 gm tube(Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% - 30 gm tube net content of active ingredients 13.636 kgs.)	1 Number	5	Nystatin USP	477.30 mg.
Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% - 60 gm tube(Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% - 60 gm tube net content of active ingredients 27.273 kgs.)	1 Number	6	Nystatin USP	954.61 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	103 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000395AM25
RA File Number	08AX04000093 AM25

Licence No and Date	0811011347/23/04/2024			
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. 3411003468 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:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Fulvestrant Injection 250 mg / 5 ML (50mg/ML)	One 5 ml. Prefilled Syringe	1	Fulvestrant USP	269.349 mg/Vial
RA concerned may take further necessary action as per above decision of NC.				

Case No.	104 / NC/3/MEET/Aug/202425/8			
Case Status	Case Approved			
Party Name	ZENITH DYEINTERMEDIATES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024			
HQ File Number	HQRNORM APPLY 00000407AM25			
RA File Number	03AX04000192 AM25			
Licence No and Date	0311033314/24/04/2024			
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/202324/11 dated 22.08.2023 against advance authorization No. 0311020392 dated 02.01.2023, 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.
NAS-5((2-DIAZO-1-NAPHTHOL-5-SULFONIC ACID, SODIUM SALT))	99900 kg.	1	Tobias Acid	161638.0 kg.

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

Case No.	105 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000408AM25
RA File Number	03AX04000290 AM25
Licence No and Date	0311033317/24/04/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	106 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000410AM25
RA File Number	52AX04000014 AM25
Licence No and Date	5211007960/24/04/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	107 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000411AM25

RA File Number	03AX04000307 AM25													
Licence No and Date	0311033331/24/04/2024													
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. 0311031952 dated 11.03.2024, 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:-														
<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>DOXYLEB CAPSULE (DOXYCYCLINE HYCLATE CAPSULE BP) 100MG(IN PACKING OF 10 X10's , 10 X 100's, 1000's QTY CONSUMED OF EXEMPT MATERIAL DOXYCYCLINE HYCLATE BP- 115.400MG/CAPSULE)</td> <td>1 Number</td> <td>1</td> <td>DOXYCYCLINE HYCLATE BP</td> <td>115.40 mg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DOXYLEB CAPSULE (DOXYCYCLINE HYCLATE CAPSULE BP) 100MG(IN PACKING OF 10 X10's , 10 X 100's, 1000's QTY CONSUMED OF EXEMPT MATERIAL DOXYCYCLINE HYCLATE BP- 115.400MG/CAPSULE)	1 Number	1	DOXYCYCLINE HYCLATE BP	115.40 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
DOXYLEB CAPSULE (DOXYCYCLINE HYCLATE CAPSULE BP) 100MG(IN PACKING OF 10 X10's , 10 X 100's, 1000's QTY CONSUMED OF EXEMPT MATERIAL DOXYCYCLINE HYCLATE BP- 115.400MG/CAPSULE)	1 Number	1	DOXYCYCLINE HYCLATE BP	115.40 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	108 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000416AM25
RA File Number	34AX04000913 AM24
Licence No and Date	3411004851/24/04/2024
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.
Acitretin Capsules USP 10 mg(Acitretin Capsules USP 10 mg (Net content of active ingredients 2.50 kgs))	1 Number	1	Acitretin USP	10.2 mg/ Capsule
Acitretin Capsules USP 17.5 mg(Acitretin Capsules USP 17.5 mg (Net content of active ingredients 6.125 kgs))	1 Number	2	Acitretin USP	17.85 mg/ Capsule
Acitretin Capsules USP 25 mg(Acitretin Capsules USP 25 mg (Net content of active ingredients 10.00 kgs))	1 Number	3	Acitretin USP	25.50 mg/ Capsule

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

Case No.	109 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	CONNEX PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000436AM25
RA File Number	26AX04000084 AM24
Licence No and Date	2611001430/25/04/2024

Norms Committee Decision:

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

- 1. Stoichiometric material balance of the reaction.**
- 2. Stage wise yield of the reaction, giving justification for overall low yield.**

Case No.	110 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000437AM25
RA File Number	03AX04000385 AM25
Licence No and Date	0311033377/26/04/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	111 / NC/3/MEET/Aug/202425/8			
Case Status	Case Approved			
Party Name	ALEMBIC PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024			
HQ File Number	HQRNORM APPLY 00000441AM25			
RA File Number	08AX04000115 AM25			
Licence No and Date	0811011386/26/04/2024			
Norms Committee Decision:				
Decision: The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-				
Sl. No.	Export Product	Qty.	Import Items	Qty. allowed.
1	Clobetasol Propionate Cream USP 0.05% 15 gm(Clobetasol Propionate Cream USP 0.05% 15 gm (net content of active ingredients 450.00 gm.))	60000.0 Numbers	CLOBETASOL PROPIONATE USP (MICRONIZED)	16238.40 gms.
2	Clobetasol Propionate Cream USP 0.05% 30	40000.0		

	gm(Clobetasol Propionate Cream USP 0.05% 30 gm (net content of active ingredients 600.00 gm.))	Numbers		
3	Clobetasol Propionate Cream USP 0.05% 45 gm(Clobetasol Propionate Cream USP 0.05% 45 gm (net content of active ingredients 1012.50 gm.))	45000.0 Numbers		
4	Clobetasol Propionate Cream USP 0.05% 60 gm(Clobetasol Propionate Cream USP 0.05% 60 gm (net content of active ingredients 1650.00 gm.))	55000.0 Numbers		
5	Clobetasol Propionate Topical Solution USP 0.05% 25ml(Clobetasol Propionate Topical Solution USP 0.05% 25ml (net content of active ingredients 625.00 gm.))	50000.0 Numbers		
6	Clobetasol Propionate Topical Solution USP 0.05% 50 ml(Clobetasol Propionate Topical Solution USP 0.05% 50 ml (net content of active ingredients 875.00 gm.))	35000.0 Numbers		
7	Clobetasol Propionate Shampoo, 0.05% 118 ml(Clobetasol Propionate Shampoo, 0.05% 118 ml (net content of active ingredients 3540.00 gm.))	60000.0 Numbers		
8	Clobetasol Propionate Spray, 0.05% - 59 ml(Clobetasol Propionate Spray, 0.05% - 59 ml (net content of active ingredients 442.50 gm.))	15000.0 Numbers		
9	Clobetasol Propionate Spray, 0.05% - 125 ml(Clobetasol Propionate Spray, 0.05% - 125 ml (net content of active ingredients 625.00 gm.))	10000.0 Numbers		
10	Clobetasol Propionate Ointment USP 0.05% 15 gm(Clobetasol Propionate Ointment USP 0.05% 15 gm (net content of	60000.0 Numbers		

	active ingredients 450.00 gm.))			
11	Clobetasol Propionate Ointment USP 0.05% 30 gm(Clobetasol Propionate OintmentUSP 0.05% 30 gm (net content of active ingredients 675.00 gm.))	45000.0 Numbers		
12	Clobetasol Propionate Ointment USP 0.05% 45 gm(Clobetasol Propionate Ointment USP 0.05% 45 gm (net content of active ingredients 675.00 gm.))	30000.0 Numbers		
13	Clobetasol Propionate Ointment USP 0.05% 60 gm(Clobetasol Propionate Ointment USP 0.05% 60 gm (net content of active ingredients 1800.00 gm.))	60000.0 Numbers		
14	Clobetasol Propionate Foam USP 0.05% 50gm.(Clobetasol Propionate Foam USP 0.05% 50gm. (net content of active ingredients 1000.00 gm.))	40000.0 Numbers		
15	Clobetasol Propionate Foam USP 0.05% 100 gm.(Clobetasol Propionate Foam USP 0.05% 100 gm. (net content of active ingredients 1500.00 gm.))	30000.0 Numbers		
RA concerned may take further necessary action as per above decision of NC.				

Case No.	112 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000450AM25
RA File Number	34AX04000063 AM25

Licence No and Date	3411004867/26/04/2024			
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. 3411003779 dated 05/06/2023, 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.
ALDEHYDE C10 (CAPRIC ALDEHYDE)	1 kg.	1	FATTY ALCOHOL C10 (98% purity)	1.40 kg.
RA concerned may take further necessary action as per above decision of NC and also check the percentage content of item at the time of export.				

Case No.	113 / NC/3/MEET/Aug/202425/8			
Case Status	Case Approved			
Party Name	TITAN LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024			
HQ File Number	HQRNORM APPLY 00000451AM25			
RA File Number	03AX04000434 AM25			
Licence No and Date	0311033398/26/04/2024			
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/202223/22 dated 24.03.2023 against advance authorization No. 0311018753 dated 20.10.2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

ORLISTAT PELLETS 50 %	1 kg.	1	ORLISTAT USP	0.505 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	114 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000455AM25
RA File Number	03AX04000337 AM25
Licence No and Date	0311033405/28/04/2024

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.3/82-ALC4/2018 dated 05/06/2018** against advance authorization **No. 0310815936 dated 25/09/2017**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ETHYL-2-BROMOBUTYRATE	1 kg.	1	N-BUTYRIC ACID	0.701 kg.
		2	LIQUID BROMINE	1.276 kg.

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

Case No.	115 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved

Party Name	KOPRAN RESEARCH LABORATORIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024										
HQ File Number	HQRNORM APPLY 00000457AM25										
RA File Number	03AX04000436 AM25										
Licence No and Date	0311033409/29/04/2024										
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. 0311029157 dated 06.12.2023, 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:- <table border="1" data-bbox="196 791 1428 986"> <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>AZITHROMYCIN DIHYDRATE</td><td>1 kg.</td><td>1</td><td>AZITHROMYCIN AMINE</td><td>0.9434 kg.</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	AZITHROMYCIN DIHYDRATE	1 kg.	1	AZITHROMYCIN AMINE	0.9434 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
AZITHROMYCIN DIHYDRATE	1 kg.	1	AZITHROMYCIN AMINE	0.9434 kg.							

Case No.	116 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000458AM25
RA File Number	03AX04000426 AM25
Licence No and Date	0311033410/29/04/2024
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. 0311029157 dated 06.12.2023, 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.
AZITHROMYCIN DIHYDRATE	1 kg.	1	AZITHROMYCIN AMINE	0.9434 kg.

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

Case No.	117 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000465AM25
RA File Number	03AX04000400 AM25
Licence No and Date	0311033430/29/04/2024

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.
DORIPENEM STERILE	200 kg.	1	MAP (METHYL VINYL PHOSPHATE: CAS NO. 189188-38-3) (4R-5S-6S-3-DIPHENYLOXY PHOSPHORYLOX-6-1R-HYDROXYETHYL-4-METHYL-7-OXO-1 AZABICYCLO 3 2 0	500 kg.
		2	DORIPENEM SIDE CHAIN (4-NITROBENZYL (2S,4S)-4-ACETYLTHIO-2-[(N-SULFAMOYL N-(TERT-BUTOXYCARBONYL) AMINO)PYRROLIDINE-1-	492.35 kg.

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

Case No.	118 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000466AM25
RA File Number	03AX04000437 AM25
Licence No and Date	0311033432/29/04/2024

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.
AZELAIC ACID GEL 15 percent (Pack Size 50 Grams) (Net Wt. of Azelaic Acid is 980.63 Kgs.)	130750 Numbers	1	Azelaic Acid	1000.24 kg.

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

Case No.	119 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	SIGNATURE PHYTOCHEMICAL INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000467AM25

RA File Number	03AX04000380 AM25
Licence No and Date	0311033435/29/04/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Drug Manufacturing Licence (DML) showing approved composition.	

Case No.	120 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000476AM25
RA File Number	08AX04000132 AM25
Licence No and Date	0811011403/29/04/2024
Norms Committee Decision: Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	121 / NC/3/MEET/Aug/202425/8
Case Status	Case Deferred
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000484AM25
RA File Number	09AX04001160 AM24
Licence No and Date	0911007159/30/04/2024
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	122 / NC/3/MEET/Aug/202425/8
Case Status	Case Approved
Party Name	INDO AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202425/ 8 and 28/08/2024
HQ File Number	HQRNORM APPLY 00000487AM25
RA File Number	03AX04000301 AM25
Licence No and Date	0311033470/30/04/2024

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.
DI BUTYL AMINO PROPYL AMINE OR IAL DBAPA	1 kg.	1	DI N BUTYL AMINE	0.788 kg.
		2	ACRYLONITRILE	0.324 kg.

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