



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 : egtf-dgft@gov.in , Phone Office : 011-23062777

(DES - III SECTION)

Minutes of Meeting

MeetingNo-NC/3/MEET/Oct/202526/9

MeetingDate-14/10/2025

Minutes of the Norms Committee-3 Meeting No.NC/3/MEET/Oct/202526/9 dated 14/10/2025 under the Chairmanship of Shri Rakesh Kumar, Addl. DGFT for considering the cases/issues under the Duty Exemption Scheme (Chapter-4) of the Foreign Trade Policy, 2023 pertaining to Chemical and Allied products falling under Chapter 29 and 30.

2. The following members were present in the Meeting:-

Sl. No.	Name & Designation	Department
1	Shri Dinesh Narain Mathur, Technical Expert	Consultant (Pharma)
2	Shri Shaish Kumar, Technical Expert	Consultant (Chemical)
3	Shri Nand Lal, Technical Expert	Consultant (Chemical)
4	Shri Raman Kumar, Deputy DGFT	DGFT (HQ)
5	Smt. Skina Rani, FTDO	DGFT (HQ)

3. The Norms Committee has taken decisions only with respect to the technical aspect/ wastage norms. While redeeming the application, RAs should check that the applicant has fulfilled all requirements as prescribed in policy/procedure, including those in notifications, public notices and policy circulars issued from time to time or any other provisions under FTP/HBP for issuance of Advance Authorization and regularisation of the case.

4. RAs shall ensure compliance with SION, General Notes and Chapter Notes wherever applicable.

5. 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 with the provisions of Para 4.12 of FTP, Para 4.16, Para 4.21, and Para 4.51 of HBP shall be made.

Case No.	1 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00001052AM26
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents from the firm: Details of Packing Material and its requirement for export item with sample.	

Case No.	2 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	INDO AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM REVIW00002408AM26
RA File Number	039404000984 AM19
Licence No and Date	0310827206/21/02/2019
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Meaning of IAL LAD in the export description.	

2. In Annexure to Appendix-4 E, the import item is shown as 'liquid' whereas in Certificate of Analysis (CoA), it is indicated as solid and same is to clarify.
3. Justification of 10.90% of wastage of raw material.

Case No.	3 / NC/3/MEET/Oct/202526/9
Case Status	Case Rejected
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM REVIW00003062AM26
RA File Number	318304000150 AM20
Licence No and Date	3110067697/25/02/2020
Norms Committee Decision: The Committee considered the firm's request for a review of the ad-hoc norms. Upon examination, it was observed that the firm had not furnished any substantive technical justification or supporting information to warrant an enhancement of the existing norms. In the absence of any new material evidence or justification, the Committee found no reasonable grounds to review or revise the norms. Accordingly, it was decided to reject the request and maintain the status quo.	

Case No.	4 / NC/3/MEET/Oct/202526/9				
Case Status	Case Approved				
Party Name	INDO AMINES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025				
HQ File Number	HQRNORM REVIW00002402AM26				
RA File Number	039404000141 AM21				
Licence No and Date	0310836585/09/06/2020				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					

		No.		
Valeronitrile	1 Kg.	1	2-Penetenenitrile	0.996 Kg.

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

Case No.	5 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	ANUH PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006659AM25
RA File Number	NA
Licence No and Date	0311000657/04/01/2021

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jun/202526/5 dated 30.06.2025 against Advance Authorisation No. 0310836875 dt. 25/06/2020 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.
Deflazacort IP/BP/EP	1 kg.	1	11 B, 16B)-Hydroxy 2-Methly-5H-Pregna-1.4Dieno (17.16D) Oxazole-3.0-Dione (D5)	1.00 kg.

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

Case No.	6 / NC/3/MEET/Oct/202526/9
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Case Status	Case Approved																
Party Name	INDO AMINES LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025																
HQ File Number	HQRNORM REVIW00002507AM26																
RA File Number	03AX04005572 AM23																
Licence No and Date	0311021737/27/02/2023																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td rowspan="2">Styrenated Phenol or IAL SP</td><td rowspan="2">1 kg.</td><td>1</td><td>Styrene</td><td>0.584 kg.</td></tr><tr><td>2</td><td>Phenol</td><td>0.257 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Styrenated Phenol or IAL SP	1 kg.	1	Styrene	0.584 kg.	2	Phenol	0.257 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Styrenated Phenol or IAL SP	1 kg.	1	Styrene	0.584 kg.													
		2	Phenol	0.257 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	7 / NC/3/MEET/Oct/202526/9
Case Status	Case Rejected
Party Name	SUPRIYA LIFESCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM REVIW00003046AM26
RA File Number	03AX04001271 AM25
Licence No and Date	0311034600/13/06/2024
Norms Committee Decision:	
The Committee considered the firm’s request for a review of the ad-hoc norms. Upon examination, it was observed that the firm had not furnished any substantive technical justification or supporting information to warrant an enhancement of the existing norms. In the absence of any new material evidence or justification, the Committee found no reasonable grounds to review or revise the norms. Accordingly, it was decided to reject the request and maintain the status quo.	

Case No.	8 / NC/3/MEET/Oct/202526/9																
Case Status	Case Approved																
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025																
HQ File Number	HQRNORM APPLY 00005564AM25																
RA File Number	03AX04004855 AM25																
Licence No and Date	0311040319/09/01/2025																
Norms Committee Decision:																	
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jul/202526/6 dated 31.07.2025 against Advance Authorisation No. 0311040267 dt. 08/01/2025, it was decided to fix ad-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">Nitrofurantoin Macrocrystals (Nitrofurantoin Anhydrous)</td><td rowspan="2">1 kg.</td><td>1</td><td>5-Nitrofurfural Diacetate</td><td>1.13 kg.</td></tr><tr><td>2</td><td>1-Aminohydantion HCl</td><td>0.59 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Nitrofurantoin Macrocrystals (Nitrofurantoin Anhydrous)	1 kg.	1	5-Nitrofurfural Diacetate	1.13 kg.	2	1-Aminohydantion HCl	0.59 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Nitrofurantoin Macrocrystals (Nitrofurantoin Anhydrous)	1 kg.	1	5-Nitrofurfural Diacetate	1.13 kg.													
		2	1-Aminohydantion HCl	0.59 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	9 / NC/3/MEET/Oct/202526/9			
Case Status	Case Approved			
Party Name	AARTI PHARMALABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025			
HQ File Number	HQRNORM APPLY 00005550AM25			
RA File Number	03AX04004964 AM25			
Licence No and Date	0311040297/09/01/2025			

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Di Ethyl Sulphate	1 kg.	1	Ethanol (Ethyl Alcohol and other Spirits Denatured of any Stregnth Denatured Ethyl Alcohol	0.703 kg.
		2	SO3	0.611 kg.
		3	Sodium Sulphate	0.114 kg.

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

Case No.	10 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006226AM25
RA File Number	03AX04005834 AM25
Licence No and Date	0311041344/14/02/2025

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under:-

Sl. No.	Export Product	Quantity
1	Medical Ointments / Creams (NITROGLYCERIN OINTMENT USP 0.4% 30 G (Tot net Wt 1200 Kgs Net Cont: SDM 27 (10% NITROGLYCERIN IN PROP.	1 Number

	GLYCOL) 48 Kgs, Pharmalan 168 Kgs, Sorbitan 24Kgs, Aluminium Tubes 40000 Nos))	
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Sl. No.	Import Product	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy & General Notes.

Note:

i. 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.	11 / NC/3/MEET/Oct/202526/9				
Case Status	Case Approved				
Party Name	MANKIND PHARMA LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025				
HQ File Number	HQRNORM APPLY 00006236AM25				
RA File Number	05AX04003948 AM25				
Licence No and Date	0511030908/14/02/2025				

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jun/202526/5 dated 30/06/2025 against Advance Authorisatgion No.0511019756 dt. 12/07/2023, 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.
Timolol Maleate Ophthalmic	51000	1	Timolol Maleate USP	0.884 kg.

Solution, USP 0.25% (5 ml.)	Numbers			
Timolol Maleate Ophthalmic Solution, USP 0.25% (10 ml.)	20000 Numbers	2	Timolol Maleate USP	0.694 kg.
Timolol Maleate Ophthalmic Solution, USP 0.5% (5 ml.)	515000 Numbers	3	Timolol Maleate USP	17860.22 gm.
Timolol Maleate Ophthalmic Solution, USP 0.5% (10 ml.)	65000 Numbers	4	Timolol Maleate USP	4508.40 gm.

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

Case No.	12 / NC/3/MEET/Oct/202526/9	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025	
HQ File Number	HQRNORM APPLY 00006244AM25	
RA File Number	03AX04005844 AM25	
Licence No and Date	0311041395/16/02/2025	
Norms Committee Decision:		
The Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under:-		
Sl. No.	Export Product	Quantity
1	Medical Creams and Onitments ("Fluorouracil Topical Solution USP 5%, 10ml Total Nt Wt. 645 Kgs (fluo 32.353 Kgs, ede 0.335 kgs, met 0.645, gly 308.981, para 0.206 Kgs, tro54.18 kgs, hyd 16.125 kg, bot 64500, drop 64500, cap 64500)")	1 Number

2	Medical Creams and Onitments ("Fluorouracil Cream USP 5% 40 Gm Total Net Wt. 8800 Kgs (fluo 440 Kgs, wh petro1848 kgs, pro gly1056 Kgs, stearyl alco 1320, poly 352 Kgs, pro para 1.32 kgs, methyl 2.200 Kgs)")	1 Number
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Sl. No.	Import Product	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy & General Notes.

Note:

i. 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.	13 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM SPECIALITIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006264AM25
RA File Number	31AX04000440 AM25
Licence No and Date	3111004443/17/02/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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2,6 Xylenol	1 kg.	1	Phenol	0.963 kg.
		2	Methanol	0.750 kg.
		3	Catalyst (Katalco)	0.004 kg.

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

Case No.	14 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM SPECIALITIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006265AM25
RA File Number	31AX04000438 AM25
Licence No and Date	3111004444/17/02/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2,6 Xylenol	1 kg.	1	Phenol	0.963 kg.
		2	Methanol	0.750 kg.
		3	Catalyst (Katalco)	0.004 kg.

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

Case No.	15 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006259AM25
RA File Number	03AX04005876 AM25
Licence No and Date	0311041412/17/02/2025

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Dec/202425/12 dated 10/12/2024 against Advance Authorisation No. 0311034851 dt. 24/06/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Idezar 150 mg Tablets 28 S (Irbesartan Tablets 150 mg 28 S) ((31,000 Boxes X 28 Tablets per Boxes = 8,68,000 Tablets) (Total Weight of Export Product = 130.200 Kgs) (Exempts imported input/material weight inclusive of wastage = 140.655 Kgs))	1 Number	1	Irbesartan Ph. Eur	153 mg.

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

Case No.	16 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025

HQ File Number	HQRNORM APPLY 00006290AM25															
RA File Number	34AX04000999 AM25															
Licence No and Date	3411006105/18/02/2025															
Norms Committee Decision:																
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under para 4.07 of hbp vol. i as per details given below or as applied by the firm, whichever is less:-																
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. Allowed.</th></tr><tr><td>Betamethasone Valerate Foam 0.12% -50 gm CAN (Net content of active ingredients 1320.00 GMS)</td><td>1 Number</td><td>1</td><td>Betamethasone Valerate USP (Micronized)</td><td>61.20 mg.</td></tr><tr><td>Betamethasone Valerate Foam 0.12% -100 gm CAN (Net content of active ingredients 2640.00 GMS)</td><td>1 Number</td><td>2</td><td>Betamethasone Valerate USP (Micronized)</td><td>122.40 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.	Betamethasone Valerate Foam 0.12% -50 gm CAN (Net content of active ingredients 1320.00 GMS)	1 Number	1	Betamethasone Valerate USP (Micronized)	61.20 mg.	Betamethasone Valerate Foam 0.12% -100 gm CAN (Net content of active ingredients 2640.00 GMS)	1 Number	2	Betamethasone Valerate USP (Micronized)	122.40 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.												
Betamethasone Valerate Foam 0.12% -50 gm CAN (Net content of active ingredients 1320.00 GMS)	1 Number	1	Betamethasone Valerate USP (Micronized)	61.20 mg.												
Betamethasone Valerate Foam 0.12% -100 gm CAN (Net content of active ingredients 2640.00 GMS)	1 Number	2	Betamethasone Valerate USP (Micronized)	122.40 mg.												
RA concerned may take further necessary action as per above decision of NC.																
Note: The committee also decided to review SION A-3690.																

Case No.	17 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006291AM25
RA File Number	03AX04005867 AM25
Licence No and Date	0311041473/18/02/2025
Norms Committee Decision: The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Apr/202526/1 dated 25/04/2025 against Advance Authorisation No. 0311037569 dt. 01/10/2024, 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:-	

Sl.No.	Export Product	Quantity
1	Natural Refined Phytosterol 95%	60000 kg.
2	Natural Mixed Tocopherol 50%	38500 kg.

Sl. No.	Import Item	Quantity
1	Fatty Acid Distillate /Deoderised Distillate	9,21,250 kg.
2	Acetone	44,000 kg.
3	N Heptane	94,050 kg.

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

Case No.	18 / NC/3/MEET/Oct/202526/9										
Case Status	Case Approved										
Party Name	METROCHEM API PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025										
HQ File Number	HQRNORM APPLY 00006305AM25										
RA File Number	26AX04000041 AM25										
Licence No and Date	2611001812/19/02/2025										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Saxagliptin intermediates (N-[2-(3-Cyano-2- Azabicyclo [3.1.0] Hexan-2-</td><td>1 kg.</td><td>1</td><td>(2S)-2-(3-hydroxy-1-adamantyl)-2-[(2-</td><td>0.98 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Saxagliptin intermediates (N-[2-(3-Cyano-2- Azabicyclo [3.1.0] Hexan-2-	1 kg.	1	(2S)-2-(3-hydroxy-1-adamantyl)-2-[(2-	0.98 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Saxagliptin intermediates (N-[2-(3-Cyano-2- Azabicyclo [3.1.0] Hexan-2-	1 kg.	1	(2S)-2-(3-hydroxy-1-adamantyl)-2-[(2-	0.98 kg.							

YL)-1-(3-Hydroxy-1-Adamantyl)-2-Oxoethyl] Carbamate (GL-III)))			methylpropan-2-yl) oxycarbonylamino] acetic acid	
		2	(1S,3S,5S)-2-azabicyclo [3.1.0] hexane-3-carboxamide; methanesulfonic acid	0.70 kg.

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

Case No.	19 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006306AM25
RA File Number	26AX04000061 AM25
Licence No and Date	2611001813/19/02/2025
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant information / documents from the firm.	
1. Complete chemistry not given. 2. Moler yields not given. 3. Solvent recovery not given. 4. Norms applied are not proportional to their molecular weight.	

Case No.	20 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	VISWAAT CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025

HQ File Number	HQRNORM APPLY 00006327AM25														
RA File Number	03AX04005955 AM25														
Licence No and Date	0311041523/20/02/2025														
Norms Committee Decision: The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Feb/202425/17 dated 25/02/2025 against Advance Authorisation No. 0311025198 dt. 06/07/2023, 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 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>Vicasol MV 06</td><td rowspan="2">750 MT</td><td>1</td><td>Ammonia Gas</td><td>15.3 MT</td></tr> <tr> <td>[Poly-Isopropanol Amines]</td><td>2</td><td>Propylene Oxide</td><td>749.7 MT</td></tr> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Vicasol MV 06	750 MT	1	Ammonia Gas	15.3 MT	[Poly-Isopropanol Amines]	2	Propylene Oxide	749.7 MT
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.											
Vicasol MV 06	750 MT	1	Ammonia Gas	15.3 MT											
[Poly-Isopropanol Amines]		2	Propylene Oxide	749.7 MT											
RA concerned may take further necessary action as per above decision of NC.															

Case No.	21 / NC/3/MEET/Oct/202526/9					
Case Status	Case Approved					
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025					
HQ File Number	HQRNORM APPLY 00006340AM25					
RA File Number	08AX04002003 AM25					
Licence No and Date	0811014208/21/02/2025					
Norms Committee Decision: The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Sep/202526/08 dated 17.09.2025 against Advance Authorisation No. 0711013550 dt. 04/02/2025, it was decided to fix ad-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 Injection 100 mg / mL (10 mL.)	21739 Vials	1	Tranexamic acid (Injectable grade, US FDA approved)	22.826 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	22 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006342AM25
RA File Number	03AX04005961 AM25
Licence No and Date	0311041536/21/02/2025

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under:-

Sl. No.	Export Product	Quantity
1	Medical Cream & Onitment(Mesalamine Rectal Suspension, USP Enema 4.0 g / 60 ml (Tot Wt: 73944 Kgs (Net Cont: Mesalamine 5028.19 Kgs, POTASSIUM METABISULFITE NF 347.17, POTASSIUM ACETATE 303.17 kgs LDPE Bottle 1200000 Nos, Enema Applicator 1200000 Nos.))	1 Number

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

Note:

- i. 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.	23 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006377AM25
RA File Number	07AX04001967 AM25
Licence No and Date	0711013735/24/02/2025

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jul/202526/6 dated 31.07.2025 against Advance Authorisation No. 0711013122 dt. 23/12/2024, 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 160 mg. ODT Premix (Each 450 mg Premix Contains 160 mg Phloroglucinol) Contents 384 kg. of Phloroglucinol)	1 Kg.	1	Phloroglucinol Dihydrate BP/EP/IP/USP)	0.359 kg.

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

Case No.	24 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025

HQ File Number	HQRNORM APPLY 00006382AM25
RA File Number	03AX04005991 AM25
Licence No and Date	0311041604/24/02/2025

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under:-

Sl. No.	Export Product	Quantity
1	Medical Cream and Onitment (Glycerine Vaseline and Paraffin Cream 250 gm [Total Wt. 750000 Kgs (Net Cont: Gly112500 Kgs, Vase 60000 Kgs, Para Liq 15000 Kgs, Ste 50% 15750 Kgs, Ste 95% 6750 Kgs, Cyclo18750 Kgs, Sili 3750 Kgs, Mac 37500 Kgs, Trie 3750 Kgs)])	1 Number

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

Note:

- i. 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.	25 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	GALAXY SURFACTANTS LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006383AM25

RA File Number	03AX04005975 AM25			
Licence No and Date	0311041607/24/02/2025			
Norms Committee Decision:				
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/May/202526/3 dated 04/06/2025 against Advance Authorisation No. 0311032511 dt. 26/03/2024, 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.
Phenoxyethanol	1 kg.	1	Phenol	0.690 kg.
		2	Ethylene Oxide	0.325 kg.

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

Note: The committee also decided to review SION A-2005.

Case No.	26 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006409AM25
RA File Number	07AX04001966 AM25
Licence No and Date	0711013758/25/02/2025
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
Import quantity is not matching with export. Complete calculation sheet in support of import quantity may be furnished.	

Case No.	27 / NC/3/MEET/Oct/202526/9			
Case Status	Case Approved			

Party Name	GALAXY SURFACTANTS LTD													
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025													
HQ File Number	HQRNORM APPLY 00006393AM25													
RA File Number	03AX04005983 AM25													
Licence No and Date	0311041620/25/02/2025													
Norms Committee Decision: The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/May/202526/3 dated 04/06/2025 against Advance Authorisation No. 0311032511 dt. 26/03/20204, it was decided to fix ad-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="2">Phenoxyethanol</td><td rowspan="2">1 kg.</td><td>1</td><td>Phenol</td><td>0.690 kg.</td></tr> <tr> <td>2</td><td>Ethylene Oxide</td><td>0.325 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.	Phenoxyethanol	1 kg.	1	Phenol	0.690 kg.	2	Ethylene Oxide	0.325 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Phenoxyethanol	1 kg.	1	Phenol	0.690 kg.										
		2	Ethylene Oxide	0.325 kg.										

Case No.	28 / NC/3/MEET/Oct/202526/9					
Case Status	Case Approved					
Party Name	GALAXY SURFACTANTS LTD					
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025					
HQ File Number	HQRNORM APPLY 00006394AM25					
RA File Number	03AX04005981 AM25					
Licence No and Date	0311041621/25/02/2025					
Norms Committee Decision: The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/May/202526/3 dated 04/06/2025 against Advance Authorisation No. 0311032511 dt. 26/03/20204, it was decided to fix ad-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.		

Phenoxyethanol	1 kg.	1	Phenol	0.690 kg.
		2	Ethylene Oxide	0.325 kg.

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

Case No.	29 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006416AM25
RA File Number	03AX04006015 AM25
Licence No and Date	0311041641/25/02/2025

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under:-

Sl. No.	Export Product	Quantity
1	Medical Cream & Ointment (TRETINOIN MICROSPHERE TOPICAL GEL 0.08% 50 Gm (Net Wt 2500 Kgs, Net cont: Tretinoin USP 2.20 Kgs, PPG-20 Methyl Glucose 118.75 Kgs, Empty Bottle 50000 Nos, Pump Over cap 50000))	1 Number
2	Medical Cream & Ointment (TRETINOIN MICROSPHERE TOPICAL GEL 0.06% 50 Gm (Net Wt 3000 Kgs, Net cont: Tretinoin USP 1.980 Kgs, PPG-20 Methyl Glucose 142.5 Kgs, Empty Bottle 60000 Nos, Pump Over cap 60000))	1 Number

Sl. No.	Import Product	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.

3	Relevant Packaging Material	Relevant as per Packing Policy & General Notes.
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Note:

i. 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.

Note: The committee also decided to review SION A-1931.

Case No.	30 / NC/3/MEET/Oct/202526/9			
Case Status	Case Approved			
Party Name	DASAMI LAB PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025			
HQ File Number	HQRNORM APPLY 00006398AM25			
RA File Number	09AX04001040 AM25			
Licence No and Date	0911009094/25/02/2025			

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Oxcarbazepine (Heterocyclic compounds with nitrogen Hetero-atom (s) Only - Compounds Containing)	1 kg.	1	10-Methoxy-5h-Dibenzo [B.F] Azepine (Diloxanidefuroate, Cimetidine , Oxyclozanide, Famotidine: Other)	1.10 kg.

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

Case No.	31 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006440AM25
RA File Number	08AX04002018 AM25
Licence No and Date	0811014244/26/02/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Nicardipine Hydrochloride Injection USP, 2.5 mg. / ml. (10 ml.)	1 Number Vial	1	Nicardipine	27.5 mg/Vial
Nicardipine Hydrochloride in 0.9% Sodium Chloride Injection, 0.2 mg. / ml. (40 mg / 200 ml.)	1 Number Vial	2	Nicardipine	42 mg/Vial
Nicardipine Hydrochloride in 0.9% Sodium Chloride Injection, 0.1 mg. / ml. (20 mg / 200 ml.)	1 Number Vial	3	Nicardipine	21 mg/Vial

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

Case No.	32 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006451AM25
RA File Number	03AX04006037 AM25
Licence No and Date	0311041670/27/02/2025

Norms Committee Decision:

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

Case No.	33 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006453AM25
RA File Number	30AX04000683 AM25
Licence No and Date	3011006585/27/02/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ceftriaxone powder for solution for injection 500 mg (Each vial contains: Ceftriaxone Sodium equivalent to ceftriaxone...500mg)	1 Number	1	Ceftriaxone Sodium Sterile	580 mg.
Ceftriaxone powder for solution for injection 1000 mg (Each vial contains: Ceftriaxone sodium Equivalent to ceftriaxone..1000 mg)	1 Number	2	Ceftriaxone Sodium Sterile	1.16 gm.
Ceftriaxone powder for solution for injection 2000 mg (Each vial contains: Ceftriaxone sodium equivalent to ceftriaxone..2000mg)	1 Number	3	Ceftriaxone Sodium Sterile	2.32 gm.

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

Case No.	34 / NC/3/MEET/Oct/202526/9															
Case Status	Case Approved															
Party Name	JUBILANT GENERICS LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025															
HQ File Number	HQRNORM APPLY 00006460AM25															
RA File Number	05AX04003972 AM25															
Licence No and Date	0511031096/27/02/2025															
Norms Committee Decision:																
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Azithromycin Tablets 250 mg</td><td>1 Number</td><td>1</td><td>Azithromycine PH.EUR (Azithromycin Dihydrate)</td><td>267.26 mg.</td></tr><tr><td>Azithromycin Tablets 500 mg</td><td>1 Number</td><td>2</td><td>Azithromycine PH.EUR (Azithromycin Dihydrate)</td><td>534.52 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Azithromycin Tablets 250 mg	1 Number	1	Azithromycine PH.EUR (Azithromycin Dihydrate)	267.26 mg.	Azithromycin Tablets 500 mg	1 Number	2	Azithromycine PH.EUR (Azithromycin Dihydrate)	534.52 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Azithromycin Tablets 250 mg	1 Number	1	Azithromycine PH.EUR (Azithromycin Dihydrate)	267.26 mg.												
Azithromycin Tablets 500 mg	1 Number	2	Azithromycine PH.EUR (Azithromycin Dihydrate)	534.52 mg.												
RA concerned may take further necessary action as per above decision of NC.																

Case No.	35 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	JUBILANT GENERICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006461AM25
RA File Number	05AX04004086 AM25
Licence No and Date	0511031098/27/02/2025
Norms Committee Decision: The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Apr/202526/1 dated 25/04/2025 against Advance Authorisation No. 0511027868 dt. 20/09/2024, 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.
Losartan Potassium 25 mg	1 Number	1	Losartan Potassium Ph.Eur (UK)	25.50 mg.
Losartan Potassium 50 mg	1 Number	2	Losartan Potassium Ph.Eur (UK)	51.00 mg.
Losartan Potassium 100 mg	1 Number	3	Losartan Potassium Ph.Eur (UK)	102.00 mg.

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

Case No.	36 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	ALKYL AMINES CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006484AM25
RA File Number	03AX04005963 AM25
Licence No and Date	0311041736/28/02/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. A balanced chemical reaction indicating molecular weight of reactants and products with yield and justification. II. Calculation of the requirement of raw materials based on yield of the reaction. III. A stoichiometric material balance on molar basis. IV. The commercial value of the by-product/s, if any, obtained during the process.	

Case No.	37 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	ATUL LIMITED
Meeting Number	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025

and Date	
HQ File Number	HQRNORM APPLY 00006517AM25
RA File Number	08AX04002033 AM25
Licence No and Date	0811014276/03/03/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. A balanced chemical reaction indicating molecular weight of reactants and products with yield and justification. 2. Calculation of the requirement of raw materials based on yield of the reaction. 3. A stoichiometric material balance on molar basis.	

Case No.	38 / NC/3/MEET/Oct/202526/9													
Case Status	Case Approved													
Party Name	SANOFI INDIA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025													
HQ File Number	HQRNORM APPLY 00006501AM25													
RA File Number	03AX04006096 AM25													
Licence No and Date	0311041778/03/03/2025													
Norms Committee Decision:														
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Dec/202425/12 dated 10/12/2024 against Advance Authorisation No. 0311034648 dt. 14/06/2024, 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Ramipril PC Granules ((Net content: each 1 gm of Ramipril 850 mg, Total net content Ramipril 5950 kg))</td><td>7000 kg.</td><td>1</td><td>Ramipril</td><td>6009.50 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ramipril PC Granules ((Net content: each 1 gm of Ramipril 850 mg, Total net content Ramipril 5950 kg))	7000 kg.	1	Ramipril	6009.50 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Ramipril PC Granules ((Net content: each 1 gm of Ramipril 850 mg, Total net content Ramipril 5950 kg))	7000 kg.	1	Ramipril	6009.50 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	39 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006498AM25
RA File Number	09AX04000930 AM25
Licence No and Date	0911009126/03/03/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dipyridamole modified release and Acetyl Salicyclic Acid Capsules 200 mg + 25 mg - Brand Name : (Orisantin 200 mg / 25 mg depotkapseli, kova/kapsel med modifierad frisattning, hard) Pack Size : 100s (Consist of 1600.00 Kgs of Dipyridamole - Ph Eur)	1 Number	1	Dipyridamole - PH Eur	204.0 mg./Capsule
Dipyridamole modified release and Acetyl Salicyclic Acid Capsules 200 mg + 25 mg - Brand Name : (Diprasorin 200 mg / 25 mg hardkapsel med modifieradfrisattning/ hardkapsel med modifieradfrisattning/ hardkapsel med modifieradfrisattning/ hardkapsel med modifieradfrisattning) Pack Size : 100s (Consist of 1600.00 Kgs of Dipyridamole - Ph Eur)	1 Number	2	Dipyridamole - PH Eur	204.0 mg./Capsule
Dipyridamole Modified Release capsules 200 mg Pack Size : 60s (Consist of 420 Kgs of Dipyridamole - Ph Eur)	1 Number	3	Dipyridamole - PH Eur	204.0 mg./Capsule

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

Case No.	40 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	ENALTEC LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025

HQ File Number	HQRNORM APPLY 00006530AM25
RA File Number	03AX04006114 AM25
Licence No and Date	0311041804/04/03/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Complete technical details as per Annexure to Appendix 4E.	

Case No.	41 / NC/3/MEET/Oct/202526/9										
Case Status	Case Approved										
Party Name	STERILE INDIA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025										
HQ File Number	HQRNORM APPLY 00006540AM25										
RA File Number	05AX04003991 AM25										
Licence No and Date	0511031191/04/03/2025										
Norms Committee Decision:											
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/May/202526/3 dated 04/06/2025 against Advance Authorisation No, 0311037863 dt. 11/10/2024, 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Meropenem Sodium Sterile (Meropenem for injection) (Containing NLT 84% Sterile Meropenem)</td><td>1 kg.</td><td>1</td><td>Meropenem Trihydrate (Non Sterile)</td><td>0.8968 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Meropenem Sodium Sterile (Meropenem for injection) (Containing NLT 84% Sterile Meropenem)	1 kg.	1	Meropenem Trihydrate (Non Sterile)	0.8968 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Meropenem Sodium Sterile (Meropenem for injection) (Containing NLT 84% Sterile Meropenem)	1 kg.	1	Meropenem Trihydrate (Non Sterile)	0.8968 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	42 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred

Party Name	LECI PURE BIOTECH LLP
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006544AM25
RA File Number	08AX04002069 AM25
Licence No and Date	0811014307/04/03/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete Certificate of Analysis (CoA) of import and export. 2. Technical difference between import and export. 3. Sample of copy of actual shipping bill and bill of entry.	

Case No.	43 / NC/3/MEET/Oct/202526/9			
Case Status	Case Approved			
Party Name	ZYDUS LIFESCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025			
HQ File Number	HQRNORM APPLY 00006549AM25			
RA File Number	08AX04002006 AM25			
Licence No and Date	0811014312/04/03/2025			
Norms Committee Decision:				
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Mar/202425/18 dated 17/03/2025 against Advance Authorisation No. 0811008323 dt. 06/06/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Norelgestromin and Ethinyl Estradiol Transdermal System 150/35 mcg. per day ((Each 15.75 CM2 Patch Contains: Norelgestromin USP 4.678 mg. to provide Norelgestromin 150 mcg./ day & Ethinyl Estradiol	1 Patch	1	Norelgestromin USP	5.8475 mg/Patch
		2	Ethinyl Estradiol USP	0.6625 mg/Patch

USP 0.53 mg. to provide Ethinyl Estradiol 35 mcg./day) (Net Wt. Norelgestromin USP - 57.545 kgs & Ethinyl Estradiol USP - 6.520 kgs))				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	44 / NC/3/MEET/Oct/202526/9
Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006529AM25
RA File Number	03AX04006135 AM25
Licence No and Date	0311041803/04/03/2025
Norms Committee Decision: The firm was granted an Advance Authorisation for the export product “<i>COUMARIN</i>” under Para 4.07 of the Handbook of Procedures (HBP). However, as per Para 4.11(b) of the Foreign Trade Policy (FTP) 2023, products falling under the category of perfume or perfumery compounds are ineligible for authorisation under Para 4.07 and are mandatorily required to be processed under Para 4.06 of the HBP. It was observed that the firm obtained the authorisation by misdeclaring that its application was covered under the provisions of Para 4.07, and has not furnished any technical justification/information for the export product. Accordingly, the Committee found no merit in fixing the norms and decided to reject the application. The RA shall ensure that the said authorisation is regularised by recovery of applicable Customs duty along with interest. Further, the RA should also submit a report on how this authorisation was issued under Para 4.07 of HBP, to the Chairperson of the Norms Committee and to PC-4 Section, DGFT Headquarters. The RA concerned may take further necessary action in line with the above decision of the Committee.	

Case No.	45 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	SV PLASTOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006571AM25
RA File Number	31AX04000435 AM25
Licence No and Date	3111004491/05/03/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete chemical name of export product along copy of shipping bill percentage yield of reaction at every stage of reaction and over all yield in the process .	

Case No.	46 / NC/3/MEET/Oct/202526/9										
Case Status	Case Approved										
Party Name	VENUS REMEDIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025										
HQ File Number	HQRNORM APPLY 00006564AM25										
RA File Number	30AX04000702 AM25										
Licence No and Date	3011006632/05/03/2025										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Topotecan Hydrochloride for Injection 4.0 mg. (Each vial contains: Topotecan Hydrochloride Equivalent to Topoteca 4 mg.)</td><td>1 Number</td><td>1</td><td>Topotecan Hydrochloride</td><td>4.78 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Topotecan Hydrochloride for Injection 4.0 mg. (Each vial contains: Topotecan Hydrochloride Equivalent to Topoteca 4 mg.)	1 Number	1	Topotecan Hydrochloride	4.78 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Topotecan Hydrochloride for Injection 4.0 mg. (Each vial contains: Topotecan Hydrochloride Equivalent to Topoteca 4 mg.)	1 Number	1	Topotecan Hydrochloride	4.78 mg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	47 / NC/3/MEET/Oct/202526/9																				
Case Status	Case Approved																				
Party Name	JUBILANT GENERICS LIMITED																				
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025																				
HQ File Number	HQRNORM APPLY 00006558AM25																				
RA File Number	05AX04004087 AM25																				
Licence No and Date	0511031203/05/03/2025																				
Norms Committee Decision:																					
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/May/202526/3 dated 04/06/2025 against Advance Authorisation No.0511028382 dated 18/11/2024; 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>Cyclobenzaprine Hydrochloride Tablets USP 5 mg.</td><td>1 Number</td><td>1</td><td>Cyclobenzaprine Hydrochloride</td><td>5.10 mg</td></tr><tr><td>Cyclobenzaprine Hydrochloride Tablets USP 7.5 mg.</td><td>1 Number</td><td>2</td><td>Cyclobenzaprine Hydrochloride</td><td>7.65 mg</td></tr><tr><td>Cyclobenzaprine Hydrochloride Tablets USP 10 mg.</td><td>1 Number</td><td>3</td><td>Cyclobenzaprine Hydrochloride</td><td>10.20 mg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Cyclobenzaprine Hydrochloride Tablets USP 5 mg.	1 Number	1	Cyclobenzaprine Hydrochloride	5.10 mg	Cyclobenzaprine Hydrochloride Tablets USP 7.5 mg.	1 Number	2	Cyclobenzaprine Hydrochloride	7.65 mg	Cyclobenzaprine Hydrochloride Tablets USP 10 mg.	1 Number	3	Cyclobenzaprine Hydrochloride	10.20 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																	
Cyclobenzaprine Hydrochloride Tablets USP 5 mg.	1 Number	1	Cyclobenzaprine Hydrochloride	5.10 mg																	
Cyclobenzaprine Hydrochloride Tablets USP 7.5 mg.	1 Number	2	Cyclobenzaprine Hydrochloride	7.65 mg																	
Cyclobenzaprine Hydrochloride Tablets USP 10 mg.	1 Number	3	Cyclobenzaprine Hydrochloride	10.20 mg																	
RA concerned may take further necessary action as per above decision of NC.																					

Case No.	48 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	JALAUQUA INTERNATIONAL LLP
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006572AM25
RA File Number	52AX04000393 AM25

Licence No and Date	5211012300/05/03/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Full chemical name of export item and to give a balanced chemical reaction indicating molecular weight of reactants and products with yield and justification. 2. Calculation of the requirement of raw materials based on yield of the reaction. 3. A stoichiometric material balance on molar basis.	

Case No.	49 / NC/3/MEET/Oct/202526/9			
Case Status	Case Approved			
Party Name	SPAR PHARMA LLP			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025			
HQ File Number	HQRNORM APPLY 00006593AM25			
RA File Number	09AX04001124 AM25			
Licence No and Date	0911009149/06/03/2025			
Norms Committee Decision:				
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jun/202526/5 dated 30/06/2025 against Advance Authorisation No. 0911008449 dated 22/11/2024, 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.
4-FLUORO-a-2-METHYL-1-OXOPROPYL)-g-OXO-N-B-DIPHENYL BENZENE BUTANEAMIDE (DIKETONE, INTERMEDIATE FOR ATORVASTATIN /DKT-3(SOLID)	1 kg.	1	Aniline Oil (Liquid)	0.47 kg.
		2	Fluorobenzene (Liquid)	0.52 kg.
		3	Acetone (Liquid)	0.50 kg.
		4	Methyl Aceto Acetate (Liquid)	1.06 kg.
		5	Iso Butyryl Chloride (Liquid)	0.97 kg.

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

Case No.	50 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	SPAR PHARMA LLP
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006592AM25
RA File Number	09AX04001125 AM25
Licence No and Date	0911009148/06/03/2025

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jun/202526/5 dated 30/06/2025 against Advance Authorisation No. 0911008449 dated 22/11/2024, 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.
4-FLUORO-a-2-METHYL-1-OXOPROPYL)-g-OXO-N-B-DIPHENYL BENZENE BUTANEAMIDE (DIKETONE, INTERMEDIATE FOR ATORVASTATIN /DKT-3(SOLID)	1 kg.	1	Aniline Oil (Liquid)	0.47 kg.
		2	Fluorobenzene (Liquid)	0.52 kg.
		3	Acetone (Liquid)	0.50 kg.
		4	Methyl Aceto Acetate (Liquid)	1.06 kg.
		5	Iso Butyryl Chloride (Liquid)	0.97 kg.

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

Case No.	51 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	MISTAIR HEALTH AND HYGIENE PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006607AM25
RA File Number	03AX04006115 AM25
Licence No and Date	0311041942/07/03/2025
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that import quantity has no match with export quantity, therefore; it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case with complete working/justification.	

Case No.	52 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	APITORIA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006613AM25
RA File Number	09AX04001129 AM25
Licence No and Date	0911009156/07/03/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Molecular weight of export product. 2. Composition of export item as used in export. 3. Certificate of Analysis (CoA) of export item to show copovidone content. 4. Recovery of solvent.	

Case No.	53 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	KLJ PETROPLAST LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006598AM25
RA File Number	05AX04004170 AM25
Licence No and Date	0511031246/07/03/2025

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jun/202526/5 dated 30/06/2025 against Advance Authorisation No. 0511028685 dt. 01/11/2024, 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.
Di-Ethyl Phthalate (DEP) (Packed In 2000 Nos. of HM-HDPE Drums made of HDPE Granules (17,000.000 Kgs. without wastage)) (each Drum shall weight 8.5 Kg and Storage Capacity 250.000 Kgs.))	1 kg.	1	Phthalic Anhydride	0.700 kg.
		2	Denatured Ethyl Alcohol	0.435 kg.
		3	HDPE Granules (Total weight =17,850.000 kg.)	As per Packing Policy and Genral Notes.

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

Case No.	54 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006602AM25
RA File Number	09AX04001103 AM25
Licence No and Date	0911009153/07/03/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
(+/-)-6,6'-Dibromo-1,1'-bi-2-naphthol (Phenols; phenol-alcohols Monophenols)	1 kg.	1	1,1 -Bi-2-Naphthol (Binol) (polyphenols)	0.72 kg.

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

Case No.	55 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	AEGIS LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006620AM25
RA File Number	08AX04002020 AM25
Licence No and Date	0811014352/10/03/2025

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jul/202526/6 dated 31/07/2025 against Advance Authorisation No.0811013741 dated 08/01/2025, it was decided to fix ad-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.
SURGI-ORC ORIGINAL 4X8 INCH (Oxidized Regenerated Cellulose)	48000 Pieces	1	Oxidized Cellulose Sheet, 10.2x20.3 cm	48000 Pieces
SURGI-ORC KNIT 3X4 INCH (Oxidized Regenerated Cellulose)	13800 Pieces	2	Oxidized Cellulose Sheet, 7,6x10,2 cm	13800 Pieces
SURGI-ORC KNIT 6X9 INCH (Oxidized Regenerated Cellulose)	3000 Pieces	3	Oxidized Cellulose Sheet, 15,2x22,9 cm	3000 Pieces
SURGI-ORC FIBRIL 2X4 INCH (Oxidized Regenerated Cellulose)	10800 Pieces	4	Oxidized Cellulose Sheet, 5,1x10,2 cm	10800 Pieces
SURGI-ORC FIBRIL 4X4 INCH (Oxidized Regenerated Cellulose)	6600 Pieces	5	Oxidized Cellulose Sheet, 10,2x10,2 cm	6600 Pieces

Oxidized Regenerated Cellulose (Oxidized Regenerated Cellulose)	5400 Pieces	6	Oxidized Cellulose Sheet 5.1X35.6 cm	5400 Pieces
SURGI-ORC ORIGINAL 2X3 INCH (Oxidized Regenerated Cellulose)	72000 Pieces	7	Oxidized cellulose sheet,, 5,1x7,6 cm	72000 Pieces

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

Case No.	56 / NC/3/MEET/Oct/202526/9																							
Case Status	Case Approved																							
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED																							
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025																							
HQ File Number	HQRNORM APPLY 00006621AM25																							
RA File Number	08AX04002085 AM25																							
Licence No and Date	0811014363/10/03/2025																							
Norms Committee Decision:																								
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Apr/202526/2 dated 08/05/2025 against Advance Authorisation No.0811012792 dt. 03/10/2024, 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>Propofol Injectable Emulsion, USP 200 mg. per 20 ml. (10 mg. per ml.)</td><td>1 Number</td><td>1</td><td>Propofol</td><td>210 mg./pack</td></tr><tr><td>Propofol Injectable Emulsion, USP 500 mg. per 50 ml. (10 mg. per ml.)</td><td>1 Number</td><td>2</td><td>Propofol</td><td>525 mg./pack</td></tr><tr><td>Propofol Injectable Emulsion, USP 1,000 mg. per 100 ml. (10 mg. per ml.)</td><td>1 Number</td><td>3</td><td>Propofol</td><td>1050 mg./pack</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Propofol Injectable Emulsion, USP 200 mg. per 20 ml. (10 mg. per ml.)	1 Number	1	Propofol	210 mg./pack	Propofol Injectable Emulsion, USP 500 mg. per 50 ml. (10 mg. per ml.)	1 Number	2	Propofol	525 mg./pack	Propofol Injectable Emulsion, USP 1,000 mg. per 100 ml. (10 mg. per ml.)	1 Number	3	Propofol	1050 mg./pack
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																				
Propofol Injectable Emulsion, USP 200 mg. per 20 ml. (10 mg. per ml.)	1 Number	1	Propofol	210 mg./pack																				
Propofol Injectable Emulsion, USP 500 mg. per 50 ml. (10 mg. per ml.)	1 Number	2	Propofol	525 mg./pack																				
Propofol Injectable Emulsion, USP 1,000 mg. per 100 ml. (10 mg. per ml.)	1 Number	3	Propofol	1050 mg./pack																				
RA concerned may take further necessary action as per above decision of NC.																								

Case No.	57 / NC/3/MEET/Oct/202526/9																
Case Status	Case Approved																
Party Name	AKIZEN LLP																
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025																
HQ File Number	HQRNORM APPLY 00006640AM25																
RA File Number	03AX04006003 AM25																
Licence No and Date	0311042019/11/03/2025																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Ethyl 4,4,4-Trifluoroacetoacetate</td><td rowspan="2">1 kg.</td><td>1</td><td>Ethyl Trifluoroacetate</td><td>0.90 kg.</td></tr><tr><td>2</td><td>Sodium Ethoxide Powder</td><td>0.47 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ethyl 4,4,4-Trifluoroacetoacetate	1 kg.	1	Ethyl Trifluoroacetate	0.90 kg.	2	Sodium Ethoxide Powder	0.47 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Ethyl 4,4,4-Trifluoroacetoacetate	1 kg.	1	Ethyl Trifluoroacetate	0.90 kg.													
		2	Sodium Ethoxide Powder	0.47 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	58 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006652AM25
RA File Number	08AX04002129 AM25
Licence No and Date	0811014389/12/03/2025
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6 mg Oral Drop ((Considering the loss on drying @14.50% of Bulk drug for 300 mg we need to poor 350.88 mg. So net content of the raw material is :- 150000 Bottles * 5 ml * 350.88 mg = 263.16 Kgs.)	150000 Numbers	1	Metamizole Magnesium	239.423 kg.
Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6 mg Oral Drop ((Considering the loss on drying @14.50% of Bulk drug for 300 mg we need to poor 350.88 mg. So net content of the raw material is :- 1500000 Bottles * 15 ml * 350.88 mg = 7894.80 Kgs.)	1500000 Numbers	2	Metamizole Magnesium	7087.50 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	59 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006676AM25
RA File Number	05AX04004149 AM25
Licence No and Date	0511031335/13/03/2025
Norms Committee Decision:	
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jun/202526/5 dated 30/06/2025 against	

Advance Authorisation No.0811009695 dt. 18/10/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cefuroxime Sodium Sterile	1 Kg.	1	Cefuroxime Acid	1.04 Kg.

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

Note: NC also decided to make new SION for the above export product.

Case No.	60 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006677AM25
RA File Number	08AX04002124 AM25
Licence No and Date	0811014404/13/03/2025

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jul/202526/6 dated 31/07/2025 against Advance Authorisation No.0811013691 dt. 03/01/2025, it was decided to fix ad-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 1000 mg per 100 ml. (10 mg/ml.)	1 Number	1	Tranexamic acid (Injectable grade, US FDA approved)	1.05 gm/100 ml Vial

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

Case No.	61 / NC/3/MEET/Oct/202526/9
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Case Status	Case Deferred
Party Name	NOVA INTERCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006700AM25
RA File Number	08AX04002133 AM25
Licence No and Date	0811014430/17/03/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Stoichiometric balance on molar basis 2. Percentage yield of reaction	

Case No.	62 / NC/3/MEET/Oct/202526/9													
Case Status	Case Approved													
Party Name	SENTISS PHARMA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025													
HQ File Number	HQRNORM APPLY 00006704AM25													
RA File Number	05AX04004167 AM25													
Licence No and Date	0511031391/17/03/2025													
Norms Committee Decision:														
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/May/202526/3 dated 04/06/2025 against Advance Authorisation No.0511028660 dt. 30/10/2024, 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Mydrimax Eye Drops 5 ml Vials (Each ml contains 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 Vials (Each ml contains 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 Vials (Each ml contains 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.	63 / NC/3/MEET/Oct/202526/9										
Case Status	Case Approved										
Party Name	AARTI PHARMALABS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025										
HQ File Number	HQRNORM APPLY 00006741AM25										
RA File Number	03AX04006239 AM25										
Licence No and Date	0311042281/19/03/2025										
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> <tr> <td>Caffeine Anhydrous</td><td>1 kg.</td><td>1</td><td>Cyano Acetic Acid 70%</td><td>0.674 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.	Caffeine Anhydrous	1 kg.	1	Cyano Acetic Acid 70%	0.674 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Caffeine Anhydrous	1 kg.	1	Cyano Acetic Acid 70%	0.674 kg.							

Case No.	64 / NC/3/MEET/Oct/202526/9										
Case Status	Case Approved										
Party Name	JUBILANT GENERICS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025										
HQ File Number	HQRNORM APPLY 00006749AM25										
RA File Number	05AX04004276 AM25										
Licence No and Date	0511031460/19/03/2025										
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> <tr> <td>Paroxetine Hydrochloride 10mg Tablets</td><td>1 Number</td><td>1</td><td>Paroxetine Hydrochloride Hemihydrate</td><td>11.609 mg.</td></tr> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Paroxetine Hydrochloride 10mg Tablets	1 Number	1	Paroxetine Hydrochloride Hemihydrate	11.609 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Paroxetine Hydrochloride 10mg Tablets	1 Number	1	Paroxetine Hydrochloride Hemihydrate	11.609 mg.							

Paroxetine Hydrochloride 20 mg Tablets	1 Number	2	Paroxetine Hydrochloride Hemihydrate	23.218 mg.
Paroxetine Hydrochloride 30 mg Tablets	1 Number	3	Paroxetine Hydrochloride Hemihydrate	34.827 mg.
Paroxetine Hydrochloride 40 mg Tablets	1 Number	4	Paroxetine Hydrochloride Hemihydrate	46.436 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	65 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	CHEMPLAST SANMAR LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006756AM25
RA File Number	04AX04001210 AM25
Licence No and Date	0411009312/19/03/2025
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
1. A balanced chemical reaction indicating molecular weight of reactants and products, with yield of the reaction and justification. 2. In the past for the export of same item, Acetone and Dimethyl Carbonate were not asked for, therefore, to give complete justification for import of these items.	

Case No.	66 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025

and Date														
HQ File Number	HQRNORM APPLY 00006740AM25													
RA File Number	30AX04000731 AM25													
Licence No and Date	3011006688/19/03/2025													
Norms Committee Decision: The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/May/202526/3 dated 04/06/2025 against Advance Authorisation No.3011005003 dt. 02/04/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <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>Sugammadex solution for Injection 100 mg / ml (200 mg / 2 ml) (Each vial of 2 ml contains: Sugammadex Sodium equivalent to sugammadex 200 mg Hydrochloric acid 3.7% (to adjust pH) and/or Sodium hydroxide (to adjust pH) Water for Injections q.s)</td> <td>1 Number</td> <td>1</td> <td>Sugammadex Sodium</td> <td>239.326 mg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sugammadex solution for Injection 100 mg / ml (200 mg / 2 ml) (Each vial of 2 ml contains: Sugammadex Sodium equivalent to sugammadex 200 mg Hydrochloric acid 3.7% (to adjust pH) and/or Sodium hydroxide (to adjust pH) Water for Injections q.s)	1 Number	1	Sugammadex Sodium	239.326 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Sugammadex solution for Injection 100 mg / ml (200 mg / 2 ml) (Each vial of 2 ml contains: Sugammadex Sodium equivalent to sugammadex 200 mg Hydrochloric acid 3.7% (to adjust pH) and/or Sodium hydroxide (to adjust pH) Water for Injections q.s)	1 Number	1	Sugammadex Sodium	239.326 mg										

Case No.	67 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006784AM25
RA File Number	03AX04006179 AM25
Licence No and Date	0311042336/20/03/2025
Norms Committee Decision: The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jun/202526/5 dated 30/06/2025 against Advance Authorisation No.0311038672 dt. 13/11/2024, 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.
Isobornyl Cyclohexanol	1 kg.	1	Gum Turpentine Oil	1.582 kg.

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

Case No.	68 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006777AM25
RA File Number	03AX04006396 AM25
Licence No and Date	0311042326/20/03/2025
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
1. Stoichiometric balance on molar basis and percentage yield to arrive at the quantity of import asked.	

Case No.	69 / NC/3/MEET/Oct/202526/9			
Case Status	Case Approved			
Party Name	JODAS EXPOIM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025			
HQ File Number	HQRNORM APPLY 00006787AM25			
RA File Number	09AX04001156 AM25			
Licence No and Date	0911009253/20/03/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Colistimethate sodium powder for preparation of solution for inhalation 1000000 Units Each vial contains: Colistimetha Sodium 1000000 Units.	300000 Numbers	1	Colistimethate Sodium	23.5475 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	70 / NC/3/MEET/Oct/202526/9			
Case Status	Case Approved			
Party Name	MANKIND PHARMA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025			
HQ File Number	HQRNORM APPLY 00006813AM25			
RA File Number	05AX04004369 AM25			
Licence No and Date	0511031520/21/03/2025			
Norms Committee Decision:				
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Jun/202526/5 dated 30/06/2025 against Advance Authorisation No.0511027226 dt. 20/08/2024, 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.
Cynacobalamin Injection USP, 1000 mcg / ml, 1ml	2275000 Numbers	1	Cyanocobalamin USP	2502.50 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	71 / NC/3/MEET/Oct/202526/9			
Case Status	Case Deferred			
Party Name	DEEPAK NITRITE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025			
HQ File Number	HQRNORM APPLY 00006815AM25			

RA File Number	34AX04001096 AM25
Licence No and Date	3411006231/21/03/2025
Norms Committee Decision:	
The Committee decided to defer the case for next meeting.	

Case No.	72 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	CONNEX PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006795AM25
RA File Number	26AX04000067 AM25
Licence No and Date	2611001859/21/03/2025
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
1. A balanced chemical reaction indicating molecular weight of reactants and products with yield and accordingly to give the requirement of raw materials. 2. Generally, the direct reaction between Methyl Chloroformate and Isopropyl Alcohol is not the standard industrial synthesis route for manufacture Chloromethyl Isopropyl Carbonate, therefore, to justify the same.	

Case No.	73 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006841AM25
RA File Number	52AX04000400 AM25
Licence No and Date	5211012552/24/03/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	74 / NC/3/MEET/Oct/202526/9															
Case Status	Case Approved															
Party Name	USV PRIVATE LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025															
HQ File Number	HQRNORM APPLY 00006844AM25															
RA File Number	03AX04006453 AM25															
Licence No and Date	0311042426/24/03/2025															
Norms Committee Decision:																
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Doxycycline Tablets, USP 50 mg 100 S((21,600 Bottles X 100 Per Bottles = 21,60,000 Tablets)</td><td>2160000 Numbers</td><td>1</td><td>Doxycycline USP (Monohydrate)</td><td>116.327 kg.</td></tr><tr><td>Doxycycline Tablets, USP 100 MG 50 S((84,000 Bottles X 50 Per Bottles = 42,00,000 Tablets)</td><td>4200000 Numbers</td><td>2</td><td>Doxycycline USP (Monohydrate)</td><td>452.382 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Doxycycline Tablets, USP 50 mg 100 S((21,600 Bottles X 100 Per Bottles = 21,60,000 Tablets)	2160000 Numbers	1	Doxycycline USP (Monohydrate)	116.327 kg.	Doxycycline Tablets, USP 100 MG 50 S((84,000 Bottles X 50 Per Bottles = 42,00,000 Tablets)	4200000 Numbers	2	Doxycycline USP (Monohydrate)	452.382 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Doxycycline Tablets, USP 50 mg 100 S((21,600 Bottles X 100 Per Bottles = 21,60,000 Tablets)	2160000 Numbers	1	Doxycycline USP (Monohydrate)	116.327 kg.												
Doxycycline Tablets, USP 100 MG 50 S((84,000 Bottles X 50 Per Bottles = 42,00,000 Tablets)	4200000 Numbers	2	Doxycycline USP (Monohydrate)	452.382 kg.												
RA concerned may take further necessary action as per above decision of NC.																

Case No.	75 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	TOPNOTCH CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006846AM25
RA File Number	03AX04006460 AM25
Licence No and Date	0311042427/24/03/2025
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Halquinol 60%	1 kg.	1	8-Hydroxy Quinoline	0.462 kg.

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

Case No.	76 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	TOPNOTCH CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006849AM25
RA File Number	03AX04006544 AM25
Licence No and Date	0311042441/24/03/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.
Lumefantrine	1 Kg.	1	9H FLUORENE	0.814 Kg.
		2	DI N Butylamine	0.390 Kg.
		3	Sodium Borohydride	0.040 Kg.
		4	Para Chloro Benzaldehyde	0.336 Kg.
		5	Di Methyl Formamide	0.555 Kg.

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

Case No.	77 / NC/3/MEET/Oct/202526/9
Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006882AM25
RA File Number	03AX04006519 AM25
Licence No and Date	0311042499/25/03/2025
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “<i>MENTHANOL</i>” (4-Isopropyl Cyclohexyl Methanol)” under Para 4.07 of the Handbook of Procedures (HBP). However, as per Para 4.11(b) of the Foreign Trade Policy (FTP) 2023, products falling under the category of perfume or perfumery compounds are ineligible for authorisation under Para 4.07 and are mandatorily required to be processed under Para 4.06 of the HBP. It was observed that the firm obtained the authorisation by misdeclaring that its application was covered under the provisions of Para 4.07, and has not furnished any technical justification/information for the export product. Accordingly, the Committee found no merit in fixing the norms and decided to reject the application. The RA shall ensure that the said authorisation is regularised by recovery of applicable Customs duty along with interest. Further, the RA should also submit a report on how this authorisation was issued under Para 4.07 of HBP, to the Chairperson of the Norms Committee and to PC-4 Section, DGFT Headquarters. The RA concerned may take further necessary action in line with the above decision of the Committee.	

Case No.	78 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006881AM25
RA File Number	05AX04004404 AM25
Licence No and Date	0511031579/25/03/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Picloxydine Ophthalmic Solution 10 ml Vial (Piclosept) - (Each ml contains 0.5 mg of Picloxydine Dihydrochloride)	1 Number	1	Picloxydine Dihydrochloride	5.10 mg.

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

Case No.	79 / NC/3/MEET/Oct/202526/9
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006854AM25
RA File Number	09AX04001173 AM25
Licence No and Date	0911009278/25/03/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Liraglutide Injection 18 mg / 3 ml (6 mg / ml) ((Each 3 ml. contains Liraglutide 18 mg.) Fill Volume- 3.3 ml.)	1 Number	1	Liraglutide (API- (Water Content- upto 10%, Acid Content- 0%, Ammonium content- 0.02%, Sodium Ion- 2.3%)=12.32%)	21.359 mg.
		2	3.0 mL Pre - Crimped Glass Siliconized Cartridge (Cartridge EZ-Fill Nexa VB 3mL)(Packing Material)	Net+1% with accountability
		3	BD Vystra Disposable Pen Body	Net+1% with

			Subassembly with purple Colour Dose Button (VYSTRA BSA FR PL 284C BTN 2685C 50 IU)(Packing Material)	accountability
		4	BD Vystra Disposable Pen Printed Cartridge Holder (VYSTRA CARTRIDGE HOLDER PRINTED 0.6-15)" (Packing Material)	Net+1% with accountability
		5	BD Vystra Disposable Pen Cap (VYSTRA CAP PL MODERN 284C) (Packing Material)	Net+1% with accountability

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

Case No.	80 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006891AM25
RA File Number	05AX04004375 AM25
Licence No and Date	0511031584/26/03/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Justification of low yield of 73.8 %	

Case No.	81 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	UNICHEM LABORATORIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006892AM25
RA File Number	03AX04006204 AM25
Licence No and Date	0311042351/26/03/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- It appears that there are 2 export items mixed together under one. Firm may be advised to get the Advanced Authorisation amended to show each export item separately with corresponding import.	

Case No.	82 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006906AM25
RA File Number	52AX04000392 AM25
Licence No and Date	5211012634/26/03/2025
Norms Committee Decision: The Committee decided to defer the case for next meeting.	

Case No.	83 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00006910AM25
RA File Number	03AX04006609 AM25
Licence No and Date	0311042574/27/03/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	

1. Complete chemistry, Molecular weight and Percentage yield on molar basis.

Case No.	84 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00000062AM26
RA File Number	03AX04006774 AM25
Licence No and Date	0311042786/02/04/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. A balanced chemical reaction indicating molecular weight of reactants and products, with yield and accordingly to give the requirement of raw materials. 2. Stoichiometric material balance on molar basis. 3. The commercial value of by-product, if any, formed during the process.	

Case No.	85 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00000064AM26
RA File Number	03AX04006769 AM25
Licence No and Date	0311042787/02/04/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. A balanced chemical reaction indicating molecular weight of reactants and products with yield and accordingly to give the requirement of raw materials.	

2. Stoichiometric material balance on molar basis.
3. The commercial value of by-product, if any, formed during the process.

Case No.	86 / NC/3/MEET/Oct/202526/9
Case Status	Case Deferred
Party Name	LA CHANDRA PHARMALAB PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202526/ 9 and 14/10/2025
HQ File Number	HQRNORM APPLY 00000242AM26
RA File Number	08AX04000065 AM26
Licence No and Date	0811014717/15/04/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete chemical description of import item. 2. Complete chemistry with molecular weight and percentage yield on molar basis. 3. Certificate of Analysis (CoA) of import item from foreign supplier.	