



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

रोड, नई दिल्ली

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(DES - III SECTION)

Meeting No -NC/3/MEET/Jun/202526/5

Meeting Date -30/06/2025

Minutes of the Norms Committee-3 Meeting No. NC/3/MEET/Jun/202526/5 dated 30/06/2025 (actually held on 04.07.2025) under the Chairmanship of Shri Rakesh Kumar, Addl. DGFT for considering the cases/issues under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy, 2023 pertaining to Chemical and Allied Products falling under Chapter 29 and 30.

2. Following members were present in the Meeting:-

Sl. No.	Name & Designation	Department
1	Shri D.N. Mathur, Technical Expert	Consultant (Pharma)
2	Shri Shaish Kumar, Technical Expert	Consultant (Chemical)
3	Shri Nand Lal, Technical Expert	Consultant (Chemical)
In attendance:		
1	Shri Raman Kumar, Deputy DGFT	DGFT (HQ)
2	Shri Uttam Dey Sarkar, ASO	DGFT (HQ)

3. The Norms Committee has taken decision only with respect to 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 regularization of the case.
4. RAs shall also ensure compliance of SION General Notes and Chapter Notes wherever applicable.
5. RAs shall ensure that authorization is issued or redeemed based on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less. In this regard full compliance of the provisions of Para 4.12 of FTP, Para 4.16; Para 4.21; and Para 4.51 of HBP shall be made.

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004170AM25
RA File Number	NA
Licence No and Date	NA

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202324/25 dated 11/03/2024 against advance authorization No.3111000876 dated 14/01/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ethylenediamine	1 kg	1	Mono Ethanol Amine	1.06 kg.
		2	Ammonia Anhydrous	0.294 kg.
Di Ethylene Triamine	1 kg	3	Mono Ethanol Amine	1.184 kg.
		4	Ammonia Anhydrous	0.165 kg.
Amino Ethyl Ethanol Amine	1 kg	5	Mono Ethanol Amine	1.173 kg.
Amino Ethyl Piperazine	1 kg	6	Mono Ethanol Amine	1.4186 kg.

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

Case No.	2 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00005879AM25
RA File Number	NA
Licence No and Date	NA
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. Label claim of Measles Vaccine Bulk in IU or other unit. 2. Process flow of manufacturing export product and stepwise wastage incurred in the manufacturing. 3. Certificate of Analysis (CoA) for the imported input products.	

Case No.	3 / NC/3/MEET/Jun/202526/5
Case Status	Case Rejected
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005286AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	4 / NC/3/MEET/Jun/202526/5
Case Status	Case Rejected
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005287AM25
RA File Number	NA
Licence No and	NA

Date	
Norms Committee Decision: The Committee considered the case as per agenda and the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	5 / NC/3/MEET/Jun/202526/5
Case Status	Case Rejected
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005288AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	6 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	STERLING AUXILIARIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005039AM25
RA File Number	039504000135 AM20
Licence No and Date	0310831916/30/09/2019
Norms Committee Decision: The committee considered the request of firm for review 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 20% wastage in chemical reaction for export item no. 2 and 3. 2. Percentage solid content of export item no.2.	

Case No.	7 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	STERLING AUXILIARIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005040AM25
RA File Number	039504000340 AM20
Licence No and Date	0310831915/30/09/2019
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Recovery of Methanol and its Commercial Value for in production of Export Product No. 1 - STEROCARE CMEA (Coco Mono Ethanol Amide).	

Case No.	8 / NC/3/MEET/Jun/202526/5										
Case Status	Case Approved										
Party Name	SRF LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025										
HQ File Number	HQRNORM REVIW00005279AM25										
RA File Number	052404000445 AM20										
Licence No and Date	0510412564/21/11/2019										
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>4,6-Dichloro-5-Fluoropyrimidine</td><td>1 kg.</td><td>1</td><td>Sodium Methoxide</td><td>1.940 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	4,6-Dichloro-5-Fluoropyrimidine	1 kg.	1	Sodium Methoxide	1.940 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
4,6-Dichloro-5-Fluoropyrimidine	1 kg.	1	Sodium Methoxide	1.940 kg.							

		2	Formamide	1.078 kg.
		3	Triethyl Amine	0.230 kg.
		4	Methanol	1.25 kg.
		5	2-Fluoro diethyl Melonate	2.133 kg.

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

Case No.	9 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	ANUH PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004744AM25
RA File Number	NA
Licence No and Date	0310836875/25/06/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202425/15 dated 28.01.2025 against advance authorization No.0511017696 dated 10/03/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Deflazacort IP/BP/EP	1 kg.	1	11 B, 16B)-HYDROXY 2-METHLY-5H-PREGNA-1.4 DIENO (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.	10 / NC/3/MEET/Jun/202526/5
Case Status	Case Rejected
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00004894AM25
RA File Number	052404000149 AM21
Licence No and Date	0510414531/01/07/2020
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	11 / NC/3/MEET/Jun/202526/5				
Case Status	Case Approved				
Party Name	SRF LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025				
HQ File Number	HQRNORM REVIW00005274AM25				
RA File Number	052404000225 AM21				
Licence No and Date	0510414951/20/08/2020				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202425/2 dated 30.04.2024 against advance authorization No.0511013749 dated 13/07/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.

3-Difluoromethyl-1-Methyl-1h-Pyrazole-4-Carboxylic Acid	1 kg.	1	Dimethyl Formamide (DMF)	0.950 kg.
		2	Sodium Methoxide Powder	0.670 kg.
		3	Acetonitrile	0.520 kg.
		4	Tri Ethyl Amine (TEA)	0.350 kg.
		5	Toluene	0.315 kg.
		6	Hydrazine Hydrate (100%)	0.668 kg.

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

Case No.	12 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	STERLING AUXILIARIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005036AM25
RA File Number	039504000492 AM21
Licence No and Date	0310839386/06/11/2020
Norms Committee Decision:	
The committee considered the request of firm for review 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 manufacturing process with chemical reaction molecular weight and percentage yield and Stoichiometric Balance. 2. Details of indigenous inputs.	

Case No.	13 / NC/3/MEET/Jun/202526/5
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Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005110AM25
RA File Number	03AA04025749 AM22
Licence No and Date	0311005018/29/06/2021
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	14 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005112AM25
RA File Number	52AA04010429 AM22
Licence No and Date	5211001058/27/07/2021
Norms Committee Decision:	
The committee considered the request of firm for review 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 for low yield reaction (56.8% & 87%) shown in first and second steps.	

Case No.	15 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005277AM25
RA File Number	05AA04071036 AM22
Licence No and Date	0511004601/08/09/2021
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.
Methoxy Trifluoro Methyl Pyridine	1 kg.	1	Trimethyl Phosphonoacetate	1.973 kg.
		2	Toluene (Bulk)	Not imported
		3	Formamide	0.662 kg.
		4	Dimethyl Formamide (DMF, Drum)	0.533 kg.
		5	N-Hexane - 95 Percent	Not imported
		6	Tri Ethyl Amine (TEA)	Not imported
		7	Potassium Carbonate Powder	Not imported
		8	Ethyl Vinyl Ether	1.133 kg.
		9	Trichloroacetyl Chloride [TCAC]	Not imported
		10	Methanol	Not imported

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

Case No.	16 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved

Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005265AM25
RA File Number	05AA04061713 AM22
Licence No and Date	0511004657/10/09/2021

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.
3-Difluoromethyl-1-Methyl-1H-Pyrazole-4-Carboxylic Acid	1 kg.	1	Dimethyl Formamide	0.950 kg.
		2	Sodium Methoxide Powder	0.670 kg.
		3	Acetonitrile	0.520 kg.
		4	Tri Ethyl Amine (TEA)	0.350 kg.
		5	Toluene	0.315 kg.
		6	Mixed Hexanes	0.236 kg.
		7	N-Butanol	0.010 kg.
		8	Hydrazine Hydrate (100 Percent)	0.668 kg.

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

Case No.	17 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved

Party Name	SRF LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025																			
HQ File Number	HQRNORM REVIW00005257AM25																			
RA File Number	05AX04000086 AM22																			
Licence No and Date	0511007243/27/12/2021																			
Norms Committee Decision:																				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																				
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="3">TESA-1-(3-Chloropyridin-2YL)-3- [5-(Trifluoromethyl) - 2H Tetrazol-2YLMethyl-1H-Pyrazole-5- Carboxylic Acid</td><td rowspan="3">1 kg.</td><td>1</td><td>HYPE</td><td>0.910 kg.</td></tr><tr><td>2</td><td>TFMT Na IN Acetone</td><td>1.91 kg.</td></tr><tr><td>3</td><td>Toluene</td><td>0.55 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	TESA-1-(3-Chloropyridin-2YL)-3- [5-(Trifluoromethyl) - 2H Tetrazol-2YLMethyl-1H-Pyrazole-5- Carboxylic Acid	1 kg.	1	HYPE	0.910 kg.	2	TFMT Na IN Acetone	1.91 kg.	3	Toluene	0.55 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
TESA-1-(3-Chloropyridin-2YL)-3- [5-(Trifluoromethyl) - 2H Tetrazol-2YLMethyl-1H-Pyrazole-5- Carboxylic Acid	1 kg.	1	HYPE	0.910 kg.																
		2	TFMT Na IN Acetone	1.91 kg.																
		3	Toluene	0.55 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	18 / NC/3/MEET/Jun/202526/5
Case Status	Case Rejected
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00004762AM25
RA File Number	07AX04000122 AM23
Licence No and Date	0711004059/23/05/2022
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo .	

Case No.	19 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	RUMIT LIFE CARE
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00004885AM25
RA File Number	03AX04001057 AM23
Licence No and Date	0311015409/10/06/2022
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. Stepwise chemical reactions, Molecular weight and percentage yield on molar basis. 2. Production/Consumption data duly certified by Chartered Accountant for the past three years.	

Case No.	20 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	STERLING AUXILIARIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005178AM25
RA File Number	03AX04002204 AM23
Licence No and Date	0311016388/15/07/2022
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has uploaded the documents for review on portal is pertains to Norms Committee-1. Therefore, the committee has decided to advise the firm to submit the proper documents for review.	

Case No.	21 / NC/3/MEET/Jun/202526/5
Case Status	Case Rejected

Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00004727AM25
RA File Number	07AX04000935 AM23
Licence No and Date	0711005338/27/09/2022
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	22 / NC/3/MEET/Jun/202526/5
Case Status	Case Rejected
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00004743AM25
RA File Number	07AX04001102 AM23
Licence No and Date	0711005565/28/10/2022
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	23 / NC/3/MEET/Jun/202526/5
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00005271AM25
RA File Number	05AX04002651 AM23
Licence No and Date	0511016260/08/12/2022
Norms Committee Decision:	

The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to **reject** the case maintaining the **status quo**.

Case No.	24 / NC/3/MEET/Jun/202526/5
Case Status	Case Rejected
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00004788AM25
RA File Number	07AX04001545 AM23
Licence No and Date	0711006198/16/01/2023
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	25 / NC/3/MEET/Jun/202526/5
Case Status	Case Rejected
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00004789AM25
RA File Number	07AX04000372 AM24
Licence No and Date	0711008298/19/06/2023
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	26 / NC/3/MEET/Jun/202526/5
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Case Status	Case Rejected
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00004729AM25
RA File Number	07AX04000426 AM24
Licence No and Date	0711008352/22/06/2023
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	27 / NC/3/MEET/Jun/202526/5																							
Case Status	Case Approved																							
Party Name	MANKIND PHARMA LIMITED																							
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025																							
HQ File Number	HQRNORM REVIW00005113AM25																							
RA File Number	05AX04001023 AM24																							
Licence No and Date	0511019756/12/07/2023																							
Norms Committee Decision:																								
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																								
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Timolol Maleate Ophthalmic Solution, USP 0.5% (5 mL)</td><td>339623 Numbers</td><td>1</td><td>Timolol Maleate USP</td><td>11778.14 gm</td></tr><tr><td>Timolol Maleate Ophthalmic Solution, USP 0.5% (10 mL)</td><td>169811 Numbers</td><td>2</td><td>Timolol Maleate USP</td><td>11778.10 gm</td></tr><tr><td>Timolol Maleate Ophthalmic Solution, USP 0.25% (5 mL)</td><td>51000 Numbers</td><td>3</td><td>Timolol Maleate USP</td><td>0.884 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Timolol Maleate Ophthalmic Solution, USP 0.5% (5 mL)	339623 Numbers	1	Timolol Maleate USP	11778.14 gm	Timolol Maleate Ophthalmic Solution, USP 0.5% (10 mL)	169811 Numbers	2	Timolol Maleate USP	11778.10 gm	Timolol Maleate Ophthalmic Solution, USP 0.25% (5 mL)	51000 Numbers	3	Timolol Maleate USP	0.884 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																				
Timolol Maleate Ophthalmic Solution, USP 0.5% (5 mL)	339623 Numbers	1	Timolol Maleate USP	11778.14 gm																				
Timolol Maleate Ophthalmic Solution, USP 0.5% (10 mL)	169811 Numbers	2	Timolol Maleate USP	11778.10 gm																				
Timolol Maleate Ophthalmic Solution, USP 0.25% (5 mL)	51000 Numbers	3	Timolol Maleate USP	0.884 kg.																				

Timolol Maleate Ophthalmic Solution, USP 0.25% (10 mL)	20000 Numbers	4	Timolol Maleate USP	0.694 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	28 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004972AM24
RA File Number	03AX04002023 AM24
Licence No and Date	0311026196/10/08/2023
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. Stepwise chemical reactions with structural formula and chemical name of each input and output product, with molecular weight. 2. Percentage yield on molar basis.	

Case No.	29 / NC/3/MEET/Jun/202526/5
Case Status	Case Rejected
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00004786AM25
RA File Number	07AX04001166 AM24
Licence No and Date	0711009545/26/10/2023
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the	

firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to **reject** the case maintaining the **status quo**.

Case No.	30 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00006520AM24
RA File Number	09AX04000671 AM24
Licence No and Date	0911006113/30/10/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Empagliflozin	1 kg.	1	Methanol	3.45 kg.
		2	Methylene Di Chloride	7.42 kg.
		3	Tetra Hydro Furan (THF)	0.88 kg.
		4	Lithium metal	0.100 kg.
		5	Acetonitrile	2.00 kg.
		6	N-Heptane	1.50 kg.
		7	(S)-3-Hydroxy Tetrahydro Furan	0.97 kg.
		8	Triethyl Silane	2.70 kg.

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

Case No.	31 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM REVIW00004787AM25
RA File Number	07AX04001679 AM24
Licence No and Date	0711010304/23/01/2024
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Copy of Drug Manufacturing License (DML) showing approved composition of each export item.	

Case No.	32 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00008252AM24
RA File Number	09AX04000962 AM24
Licence No and Date	0911006666/31/01/2024
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/18 dated 17/03/2025 against advance authorization No.0911006227 dated 14/11/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Vonoprazan Fumarate	1 kg.	1	2-Fluoro Acetophenone	0.860 kg.
		2	Pyridine 3 sulfonyl chloride	0.856 kg.
		3	Tetrahydrofuran	3.29 kg.
		4	Methylene Di Chloride	3.80 kg.
		5	Sodium Borohydrate	0.22 kg.
		6	Potassium Carbonate	0.66 kg.
		7	Di Methyl sulfoxide	1.00 kg.

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

Case No.	33 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00003967AM25
RA File Number	05AX04002513 AM25
Licence No and Date	0511028684/01/11/2024
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/13 dated 07/01/2025 against advance authorization No.0511026754 dated 19/07/2024, 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.
Nitroglycerin Sublingual Tablets USP, 0.3mg	1 Number	1	Diluted Nitroglycerin USP (2% w/w)	15.30 mg.
Nitroglycerin Sublingual Tablets USP, 0.4mg	1 Number	2	Diluted Nitroglycerin USP (2% w/w)	20.40 mg.
Nitroglycerin Sublingual Tablets USP, 0.6mg	1 Number	3	Diluted Nitroglycerin USP (2% w/w)	30.60 mg.

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

Case No.	34 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	KLJ PETROPLAST LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00003968AM25
RA File Number	05AX04002476 AM25
Licence No and Date	0511028685/01/11/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against DGFT Hqr. File No.HQRNORMREVIW00006341AM25, 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	1 kg.	1	Phthalic Anhydride	0.700 kg.

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.))		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.	35 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00003973AM25
RA File Number	03AX04003873 AM25
Licence No and Date	0311038428/04/11/2024
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
1. Copy of Drug Manufacturing Licence (DML). 2. Copy of Master-Batch Formula for each export product.	

Case No.	36 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00003974AM25
RA File Number	05AX04002518 AM25
Licence No and	0511028694/04/11/2024

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jun/202324/8 dated 30/06/2023 against advance authorization No.0511018335 dated 17/04/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty.
Cefuroxime Sodium Sterile	1 Kg.	1	Cefuroxime Acid	1.04 Kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	37 / NC/3/MEET/Jun/202526/5			
Case Status	Case Approved			
Party Name	AARTI DRUGS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025			
HQ File Number	HQRNORM APPLY 00003983AM25			
RA File Number	03AX04003864 AM25			
Licence No and Date	0311038449/04/11/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/3 dated 07/01/2025 against advance authorization No.0311035695 dated 22/07/2024, 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.
Ciprofloxacin Hydrochloride IP/BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg.

		2	Piperazine (68%)	0.574 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	38 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	KLJ PETROPLAST LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00003984AM25
RA File Number	05AX04002475 AM25
Licence No and Date	0511028726/05/11/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against DGFT Hqr. File No.HQRNORMREVIW00006341AM25, 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)	1 kg.	1	Phthalic Anhydride	0.700 kg.
		2	Denatured Ethyl Alcohol	0.435 kg.

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

Case No.	39 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved

Party Name	RASULA PHARMACEUTICALS AND FINE CHEMICALS										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025										
HQ File Number	HQRNORM APPLY 00003993AM25										
RA File Number	09AX04000607 AM25										
Licence No and Date	0911008315/06/11/2024										
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="197 714 1431 1025"> <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>Methyl Paraben BP/USP/NF/ Para Hydroxy Benzoate BP/ Methyl Para Hydroxy Benzoate Ph.Eur</td><td>1 kg.</td><td>1</td><td>Para Hydroxy Benzoic Acid PHBA</td><td>0.95 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.	Methyl Paraben BP/USP/NF/ Para Hydroxy Benzoate BP/ Methyl Para Hydroxy Benzoate Ph.Eur	1 kg.	1	Para Hydroxy Benzoic Acid PHBA	0.95 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Methyl Paraben BP/USP/NF/ Para Hydroxy Benzoate BP/ Methyl Para Hydroxy Benzoate Ph.Eur	1 kg.	1	Para Hydroxy Benzoic Acid PHBA	0.95 kg.							

Case No.	40 / NC/3/MEET/Jun/202526/5					
Case Status	Case Approved					
Party Name	MICRO LABS LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025					
HQ File Number	HQRNORM APPLY 00003999AM25					
RA File Number	07AX04001233 AM25					
Licence No and Date	0711012713/06/11/2024					
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="197 1907 1431 2004"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> </tbody> </table>		Export Product	Qty.	Sl.	Import Items	Qty. allowed.
Export Product	Qty.	Sl.	Import Items	Qty. allowed.		

		No.		
Olopatadine Hydrochloride Ophthalmic Solution 0.1%W/V 5ml (Each MI Contains 1.11 mg of Olopatadine Hydrochloride) (Net Contents :1884.86 Gms))	1 Number	1	Olopatadine Hydrochloride BP/EP/IP/USP	5.661 mg.
Olopatadine Hydrochloride Ophthalmic Solution 0.2 %W/V 2.5ml (Each MI Contains 2.22 mg of Olopatadine Hydrochloride (Net Contents : 1438.89 Gms)	1 Number	2	Olopatadine Hydrochloride BP/EP/IP/USP	5.661 mg.

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

Case No.	41 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004004AM25
RA File Number	03AX04003907 AM25
Licence No and Date	0311038503/06/11/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Desipramine Hydrochloride Tablets, USP 10 Mg 100 S((8,000 Bottles X 100 Per Bottles = 8,00,000 Tablets)	1 Number	1	Desipramine HCL USP	10.2 mg/Tablet

(Total Weight of Export Product = 8.000 Kgs) (Net Content weight of Import Product = 8.471 kgs))				
Desipramine Hydrochloride Tablets, USP 25 Mg 100 S((6,000 Bottles X 100 Per Bottles = 6,00,000 Tablets) (Total Weight of Export Product = 15.000 Kgs) (Net Content weight of Import Product = 15.884 kgs))	1 Number	2	Desipramine HCL USP	25.50 mg/Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	42 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004012AM25
RA File Number	03AX04003860 AM25
Licence No and Date	0311038515/06/11/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Gentamicin Eye/Ear Drops 10 Ml (Bactigen Eye/Ear Drops 10 Ml) ((Each Vial Contains Gentamicin Sulphate 0.030 Gm Net Wt of Bulk Drug is 3.420 Kgs))	1 Number	2	Gentamicin Sulphate(API)	36.754 mg/10 ml.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	43 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	UNIMAX LABORATORIES
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004021AM25
RA File Number	05AX04002556 AM25
Licence No and Date	0511028766/07/11/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Spiramycin Tablets 1.5 MIU (Each tablet contains Spiramycin EP)	1 Number	1	Spiramycin EP	373.02 mg/Tablet
Spiramycin Tablets 3.0 MIU (Each tablet contains Spiramycin EP)	1 Number	2	Spiramycin EP	746.04 mg/Tablet

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

Case No.	44 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004024AM25
RA File Number	34AX04000672 AM25
Licence No and Date	3411005648/07/11/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aug/202425/8 dated 28/08/2024 against advance authorization No.0811011317 dated 18/04/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Minoxidil Topical Aerosol 5% (Foam) 60 Gm CAN)	1 Number	1	Minoxidil USP	3.06 gm.

Note: The Committee also decided to fix a SION for above export product.

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

Case No.	45 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	CADCHEM LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004027AM25
RA File Number	30AX04000395 AM25
Licence No and	3011006010/07/11/2024

Date														
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202324/1 dated 28/04/2023 against advance authorization No. 0311019771 dated 06/12/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>Benfotiamine</td> <td>1 kg</td> <td>1</td> <td>Thiamine Hydrochloride (Vitamin B1 HCL)</td> <td>0.922 kg.</td> </tr> </tbody> </table> Note: The Committee also decided to fix a SION for above export product. RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty.	Benfotiamine	1 kg	1	Thiamine Hydrochloride (Vitamin B1 HCL)	0.922 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
Benfotiamine	1 kg	1	Thiamine Hydrochloride (Vitamin B1 HCL)	0.922 kg.										

Case No.	46 / NC/3/MEET/Jun/202526/5								
Case Status	Case Approved								
Party Name	ALEMBIC PHARMACEUTICALS LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025								
HQ File Number	HQRNORM APPLY 00004029AM25								
RA File Number	34AX04000675 AM25								
Licence No and Date	3411005651/07/11/2024								
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <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.					

Fulvestrant Injection 250 mg / 5 ML (50mg/ML)	1 Number	1	Fulvestrant USP	262.3 mg/Vial
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RA concerned may take further necessary action as per above decision of NC.

Case No.	47 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004046AM25
RA File Number	30AX04000419 AM25
Licence No and Date	3011006022/08/11/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 3011005556 dated 02/08/2024, 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
Ceftazidime Powder for Solution for Injection or Infusion 1.0 g (Each Vial Contains: Ceftazidime (as pentahydrate) 1g with sodium carbonate (118 mg per gram of ceftazidime Containing 50.005 Kg of Ceftazidime Pentahydrate with Sodium Carbonate Sterile)	1 Number	1	Ceftazidime Pentahydrate with Sodium Carbonate Sterile	1.258 gm.
Ceftazidime Powder for Solution for Injection or Infusion 2.0 g (Each Vial Contains: Ceftazidime (as pentahydrate) 2g with sodium	1 Number	2	Ceftazidime Pentahydrate with Sodium Carbonate Sterile	2.516 gm.

carbonate (118 mg per gram of ceftazidime Containing 50.003 Kg of Ceftazidime Pentahydrate with Sodium Carbonate Sterile)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	48 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	MANGALAM ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004063AM25
RA File Number	03AX04002657 AM25
Licence No and Date	0311038605/11/11/2024
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
Percentage yield of reaction with molecular weight of export and import items.	

Case No.	49 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	ARESKO LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004065AM25
RA File Number	05AX04002537 AM25
Licence No and Date	0511028833/11/11/2024
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the	

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

1. Complete and Balanced chemical reaction with molecular weight and percentage yield on molar basis for each export item separately.
2. Past Production/Consumption certificate for last three years for each export item.

Case No.	50 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	ZEOLITES AND ALLIED PRODUCTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004069AM25
RA File Number	03AX04003739 AM25
Licence No and Date	0311038608/11/11/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No. 0311029806 dated 01/01/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed
Cyclopentanone	1 kg.	1	Adipic Acid	1.93 kg.

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

Case No.	51 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	SYNERGIA SCIENCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004086AM25
RA File Number	03AX04003672 AM25
Licence No and Date	0311038648/12/11/2024
Norms Committee Decision: The committee considered the request of firm for review/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. As per details submitted item is manufactured from either import item No.1 or import item no. 2 & 3. 2. As such quantity of export made from import item No.1 and quantity of export made from import item no.2 & 3.	

Case No.	52 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004088AM25
RA File Number	03AX04003955 AM25
Licence No and Date	0311038649/12/11/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

200.00 Grams))				
Ipratropium Bromide/ Fenoterol Hydrobromide Pressurised Inhalation Solution 20ug/50ug per actuation (3 x 200 MDI) (Net Wt. of Fenoterol Hydrobromide is Qty. 750.00 Grams and Ipratropium Bromide is Qty. 300.00 Grams))	25000 Numbers	3	Fenoterol Hydrobromide	765.00 gm.
		4	Ipratropium Bromide	306.00 gm.

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

Case No.	53 / NC/3/MEET/Jun/202526/5										
Case Status	Case Approved										
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025										
HQ File Number	HQRNORM APPLY 00004116AM25										
RA File Number	03AX04003746 AM25										
Licence No and Date	0311038672/13/11/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/12 dated 10/12/2024 against advance authorization No. 0311035090 dated 01/07/2024, 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>Isobornyl Cyclohexanol</td><td>1 kg.</td><td>1</td><td>Gum Turpentine Oil</td><td>1.582 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	Isobornyl Cyclohexanol	1 kg.	1	Gum Turpentine Oil	1.582 kg.
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.	54 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004168AM25
RA File Number	03AX04004042 AM25
Licence No and Date	0311038743/18/11/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No. 0311037957 dated 15/10/2024, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Azithromycin Dihydrate	1 kg	1	Azithromycin Amine	0.9434 kg.

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

Case No.	55 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004178AM25
RA File Number	03AX04004070 AM25
Licence No and Date	0311038776/18/11/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No. 0311038044 dated 18/10/2024, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed
Ethyl Isobutyrate	1 kg.	1	Isobutyric Acid	0.948 kg.

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

Case No.	56 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	STERMONE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004192AM25
RA File Number	34AX04000685 AM25
Licence No and Date	3411005667/18/11/2024

Norms Committee Decision:

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

1. Complete and Balanced chemical reaction, with molecular weight.
2. Percentage yield on molar basis.

Case No.	57 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004195AM25
RA File Number	03AX04004115 AM25
Licence No and Date	0311038791/18/11/2024

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 Ointment (Erythromycin BPO and Benzoyl Peroxide GeL 0.1%/2.5% 23.3 Kit pack Tot Wt : 1165 Kgs (Net Cont: Hyd 77.70Kgs, Car 14Kgs, Docu 2.5Kgs, d lim 2.5 Kgs, Alco149.80 Kgs, Ery 1.20 Kgs, Vial 50000 nos, Seal 50000 nos, Colts 50000 nos , Jar 50000 nos, RIB 50000))	1 Number
2	Medical Cream and Ointment (Erythromycin BPO and Benzoyl Peroxide GeL 0.1%/2.5% 46.6 Gm Kit pack Tot Wt :2330 Kgs (Net Cont: Hyd 155.40 Kgs, Car 28 Kgs, Docu 5Kgs ,d lim 5 Kgs, Alco 299.60 Kgs, Ery 2.40 Kgs, Vial 50000 nos, Seal 50000 nos, Colts 50000 nos, Jar 50000 nos, RIB 50000))	1 Number

S. No	Import Product	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy & 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.	58 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004214AM25
RA File Number	05AX04002700 AM25
Licence No and Date	0511029003/19/11/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Detailed justification for the quantitative requirement of packing materials.	

Case No.	59 / NC/3/MEET/Jun/202526/5										
Case Status	Case Approved										
Party Name	ALEMBIC PHARMACEUTICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025										
HQ File Number	HQRNORM APPLY 00004218AM25										
RA File Number	34AX04000699 AM25										
Licence No and Date	3411005675/19/11/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202324/25 dated 11/03/2024 against advance authorization No. 34110043 dated 07/11/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Lidocaine and Prilocaine Cream USP 2.5% and</td><td>400000</td><td>1</td><td>Lidocaine USP</td><td>50.99 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Lidocaine and Prilocaine Cream USP 2.5% and	400000	1	Lidocaine USP	50.99 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Lidocaine and Prilocaine Cream USP 2.5% and	400000	1	Lidocaine USP	50.99 kg.							

2.5% 5 gm Tube (Net content of active ingredients 125.00 kgs and 125.00 kgs)	Numbers	2	Prilocaine Base USP	50.99 kg.
Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 30 gm tube (Net content of active ingredients 862.500 kgs and 862.500 kgs)	560000 Numbers	3	Lidocaine USP	428.39 kg.
		4	Prilocaine Base USP	428.39 kg.
Lidocaine Ointment USP 5% 30 gm tube (Net content of active ingredients 7.5 kgs)	50000 Numbers	5	Lidocaine USP	76.40 kg.
Lidocaine Ointment USP 5% 35.44 gm tube (Net content of active ingredients 8.86 kgs)	60000 Numbers	6	Lidocaine USP	108.36 kg.
Lidocaine Ointment USP 5% 50 gm jar (Net content of active ingredients 12.50 kgs)	50000 Numbers	7	Lidocaine USP	127.40 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	60 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004262AM25
RA File Number	30AX04000446 AM25
Licence No and Date	3011006063/21/11/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Copy of Certificate of Analysis (CoA) of import item from Foreign Supplier.	

Case No.	61 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004278AM25
RA File Number	34AX04000703 AM25
Licence No and Date	3411005691/21/11/2024
Norms Committee Decision: The Committee considered the request of the firm for fixation of ad-hoc norms and on the basis of information provided by the firm and it has been observed by the committee that export product “Allyl Amyl Glyolate” (Perfumery Compound) as applied by the firm appears to fall under para 4.11(b) of FTP, 2023, and the said para states that “For export of perfumes, perfumery compounds and various feeding redients containing vitamins, no authorisation shall be issued by Regional Authority under para 4.07 of HBP. The applicant firm is requested to clarify how this application comes under Para 4.07 of HBP, and the RA concerned is also directed to provide their comments on the same.	

Case No.	62 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004279AM25
RA File Number	34AX04000704 AM25
Licence No and Date	3411005693/21/11/2024
Norms Committee Decision: The Committee considered the request of the firm for fixation of ad-hoc norms and on the basis of information provided by the firm and it has been observed by the committee that export product “Em Butanoate (Ethyl-2-Methyl-Butyrate)” (Perfumery Compound) as applied by the firm appears to fall under para 4.11(b) of FTP, 2023, and the said para states that “For export of perfumes, perfumery compounds and various feeding redients containing vitamins, no authorisation shall be issued by Regional Authority under para 4.07 of HBP. The applicant firm is requested to clarify how this application comes under Para 4.07 of HBP, and the RA concerned is also directed to provide their comments on the same.	

Case No.	63 / NC/3/MEET/Jun/202526/5													
Case Status	Case Approved													
Party Name	AARTI PHARMALABS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025													
HQ File Number	HQRNORM APPLY 00004287AM25													
RA File Number	03AX04004231 AM25													
Licence No and Date	0311038930/22/11/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Theophylline (Anhydrous)</td><td>1 kg.</td><td>1</td><td>Cyano Acetic Acid 70%</td><td>0.89 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Theophylline (Anhydrous)	1 kg.	1	Cyano Acetic Acid 70%	0.89 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Theophylline (Anhydrous)	1 kg.	1	Cyano Acetic Acid 70%	0.89 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	64 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	SPAR PHARMA LLP
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004288AM25
RA File Number	09AX04000741 AM25
Licence No and Date	0911008449/22/11/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No. 0911006814 dated 21/02/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-Fluoro-alpha-[2-methyl-1-oxopropyl]-gamma-oxo-N-beta-diphenyl benzene butanamide (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.	65 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004290AM25
RA File Number	05AX04002802 AM25
Licence No and Date	0511029111/22/11/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Senticort (Budesonide Nebuliser	1 Number	1	Budisonide Ph.Eur	0.525 mg.

Suspension 0.5 mg / 2 mL Suspension) in 3 ml Ampoule				
Senticort (Budesonide Nebuliser Suspension 1.0 mg / 2mL Suspension) in 3 ml Ampoule	1 Number	2	Budisonide Ph.Eur	1.05 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	66 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	MAC-CHEM PRODUCTS (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004291AM25
RA File Number	03AX04004099 AM25
Licence No and Date	0311038941/22/11/2024
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
1. Copy of Drug Manufacturing License (DML) with approved composition of export item. 2. Copy of Master Batch Formula. 3. Vial size in ml. 4. Wastage claimed.	

Case No.	67 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	AKSHAY INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004292AM25
RA File Number	31AX04000218 AM24

Licence No and Date	3111004111/22/11/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Chloral	1 kg.	1	Denatured Ethyl Alcohol	0.375 kg.
Ethyl Chloride	1 kg.	2	Denatured Ethyl Alcohol	0.833 kg.

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

Case No.	68 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	ASTA BIOCHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004300AM25
RA File Number	07AX04001295 AM25
Licence No and Date	0711012868/22/11/2024
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	69 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004302AM25
RA File Number	05AX04002820 AM25

Licence No and Date	0511029128/22/11/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202526/2 dated 08/05/2025 against advance authorization No. 0511014976 dated 23/09/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Tobramycin Inhalation Solution, 300 mg / 5ml (Having net content of 98.82 kg of Bulk drug (filling volume 5.4 ml in each number))</td><td>1 Number Pack</td><td>1</td><td>Tobramycin USP</td><td>315 mg./Vial</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Tobramycin Inhalation Solution, 300 mg / 5ml (Having net content of 98.82 kg of Bulk drug (filling volume 5.4 ml in each number))	1 Number Pack	1	Tobramycin USP	315 mg./Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Tobramycin Inhalation Solution, 300 mg / 5ml (Having net content of 98.82 kg of Bulk drug (filling volume 5.4 ml in each number))	1 Number Pack	1	Tobramycin USP	315 mg./Vial										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	70 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	MOREPEN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004305AM25
RA File Number	05AX04002794 AM25
Licence No and Date	0511029135/22/11/2024
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	71 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004315AM25
RA File Number	34AX04000689 AM25
Licence No and Date	3411005705/22/11/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	72 / NC/3/MEET/Jun/202526/5													
Case Status	Case Approved													
Party Name	WEST BENGAL CHEMICAL INDUSTRIES LTD.													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025													
HQ File Number	HQRNORM APPLY 00004317AM25													
RA File Number	02AX04000534 AM25													
Licence No and Date	0211007647/22/11/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No. 0211007515 dated 28/10/2024, 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>Ferric Maltol</td><td>1 kg.</td><td>1</td><td>Maltol</td><td>0.962 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	Ferric Maltol	1 kg.	1	Maltol	0.962 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed										
Ferric Maltol	1 kg.	1	Maltol	0.962 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	73 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004318AM25
RA File Number	07AX04001351 AM25
Licence No and Date	0711012875/22/11/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	74 / NC/3/MEET/Jun/202526/5																				
Case Status	Case Approved																				
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED																				
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025																				
HQ File Number	HQRNORM APPLY 00004321AM25																				
RA File Number	03AX04004113 AM25																				
Licence No and Date	0311038981/24/11/2024																				
Norms Committee Decision:																					
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No. 0311022935 dated 19/04/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																					
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Tylosin Bolus 200 mg. ((Each Bolus Contains Tylosin 200mg)</td><td>1 Number</td><td>1</td><td>Tylosin Tartrate</td><td>204.00 mg.</td></tr><tr><td>Tylosin Injection 5% - 50 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin Base 50mg)</td><td>1 Number</td><td>2</td><td>Tylosin Tartrate</td><td>3.056 gm.</td></tr><tr><td>Tylosin Injection 5% - 100 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin Base 50mg)</td><td>1 Number</td><td>3</td><td>Tylosin Tartrate</td><td>6.111 gm.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Tylosin Bolus 200 mg. ((Each Bolus Contains Tylosin 200mg)	1 Number	1	Tylosin Tartrate	204.00 mg.	Tylosin Injection 5% - 50 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin Base 50mg)	1 Number	2	Tylosin Tartrate	3.056 gm.	Tylosin Injection 5% - 100 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin Base 50mg)	1 Number	3	Tylosin Tartrate	6.111 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																	
Tylosin Bolus 200 mg. ((Each Bolus Contains Tylosin 200mg)	1 Number	1	Tylosin Tartrate	204.00 mg.																	
Tylosin Injection 5% - 50 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin Base 50mg)	1 Number	2	Tylosin Tartrate	3.056 gm.																	
Tylosin Injection 5% - 100 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin Base 50mg)	1 Number	3	Tylosin Tartrate	6.111 gm.																	

Tylosin Tartrate Injection 20% - 50 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin 200mg)	1 Number	4	Tylosin Tartrate	12.222 gm.
Tylosin Tartrate Injection 20%-100 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin 200mg)	1 Number	5	Tylosin Tartrate	24.444 gm.
Tylosin Tartrate Powder 100% -100 gm. Sachet ((Each Gram Contains Tylosin Tartrate 100%)	1 Number	6	Tylosin Tartrate	101 gm.
Tylosin Tartrate Powder 100% - 500 gm. Sachet ((Each Gram Contains Tylosin Tartrate 100%)	1 Number	7	Tylosin Tartrate	505 gm.
Tylosin Tartrate Powder 100% -1 kg Jar ((Each Gram Contains Tylosin Tartrate 100%)	1 Number	8	Tylosin Tartrate	1010 gm.
Tylosin Tartrate Powder 20% -5 gm. ((Each Gram Contains Tylosin Tartrate Eq. To Tylosin 20%)	1 Number	9	Tylosin Tartrate	1.1756 gm.
Tylosin Tartrate Powder 20% -100 gm. ((Each Gram Contains Tylosin Tartrate Eq. To Tylosin 20%)	1 Number	10	Tylosin Tartrate	23.513 gm.
Tylosin Tartrate Powder 20% - 500 gm. ((Each Gram Contains Tylosin Tartrate Eq. To Tylosin 20%)	1 Number	11	Tylosin Tartrate	117.564 gm.
Tylosin Tartrate Powder 20% -1kg Jar ((Each Gram Contains Tylosin Tartrate Eq. To Tylosin 20%)	1 Number	12	Tylosin Tartrate	235.128 gm.
Tylosin Tartrate Powder 99% - 100 gm Sachet ((Each Gram Contains Tylosin Tartrate 99%)	1 Number	13	Tylosin Tartrate	100 gm.

Tylosin Tartrate Powder 99% - 500 gm Sachet ((Each Gram Contains Tylosin Tartrate 99%))	1 Number	14	Tylosin Tartrate	500 gm.
Tylosin Tartrate Powder 99% -1 kg Jar ((Each Gram Contains Tylosin Tartrate 99%))	1 Number	15	Tylosin Tartrate	1000 gm.
Tylosin Tartrate Bolus 600 mg ((Each Bolus Contains Tylosin Tartrate 600 mg))	1 Number	16	Tylosin Tartrate	612 mg.

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

Case No.	75 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	VINS BIOPRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004340AM25
RA File Number	09AX04000743 AM25
Licence No and Date	0911008471/25/11/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/18 dated 17/03/2025 against advance authorization No. 0911004801 dated 10/04/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tetanus Antitoxin I.H.S / B.P 1500 IU / ML Plus [overage of 150 IU in addition] in PFS / vials / Ampoule) [733333 Vials]	1,00,000 Vials	1	Tetanus Antitoxin 2500 I.U / ml	69.3 Liter

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

Case No.	76 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004342AM25
RA File Number	09AX04000768 AM25
Licence No and Date	0911008474/25/11/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	77 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004352AM25
RA File Number	08AX04001406 AM25
Licence No and Date	0811013327/26/11/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No. 0811010470 dated 09/01/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Dimenhydrinate 20 Mg + 40 Mg Tablets (Cinzator) (Each Uncoated Tablets Contains: Cinnarizine Ph. Eur. 20 Mg & 40 Mg Dimenhydrinate Ph. Eur. 40 Mg Net content of Dimenhydrinate should not be less than 293.530 Kgs in export product)			PH.EUR	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	78 / NC/3/MEET/Jun/202526/5													
Case Status	Case Approved													
Party Name	GALAXY SURFACTANTS LTD													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025													
HQ File Number	HQRNORM APPLY 00004373AM25													
RA File Number	03AX04004236 AM25													
Licence No and Date	0311039071/27/11/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No. 0311032511 dated 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:-														
<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">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></table>		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.										

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

Case No.	79 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004377AM25
RA File Number	08AX04001410 AM25
Licence No and Date	0811013343/27/11/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Loratadine Tablets -10 Mg (Pollentyme Tablets 10 Mg) (Each Film Coated Sustained Release Tablet Contains: Loratadine Tablets. Net Content of Active Ingredient Loratadine should not be less than 15.000 Kgs.)	1 Number	1	Loratadine (Micronised)	10.20 mg/Tablet

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

Case No.	80 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	INDO AMINES LIMITED
Meeting Number	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025

and Date														
HQ File Number	HQRNORM APPLY 00004382AM25													
RA File Number	03AX04004287 AM25													
Licence No and Date	0311039086/27/11/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No.0311037167 dated 16/09/2024, 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:-														
<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">Sorbitan Mono Laurate or IAL SML</td><td rowspan="2">1 kg.</td><td>1</td><td>Sorbitol 70% Solution</td><td>0.71 kg.</td></tr><tr><td>2</td><td>Distilled Coconut Fatty Acid (95% Active Content)</td><td>0.66 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sorbitan Mono Laurate or IAL SML	1 kg.	1	Sorbitol 70% Solution	0.71 kg.	2	Distilled Coconut Fatty Acid (95% Active Content)	0.66 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Sorbitan Mono Laurate or IAL SML	1 kg.	1	Sorbitol 70% Solution	0.71 kg.										
		2	Distilled Coconut Fatty Acid (95% Active Content)	0.66 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	81 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004386AM25
RA File Number	03AX04004293 AM25
Licence No and Date	0311039087/27/11/2024
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No. 0311038044 dated 18/10/2024, 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:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.
Ethyl Isobutyrate	1 kg.	1	Isobutyric Acid	0.948 kg.

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

Case No.	82 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	HARMONY ORGANICS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004392AM25
RA File Number	31AX04000298 AM25
Licence No and Date	3111004132/28/11/2024
Norms Committee Decision: The Committee considered the request of the firm for fixation of ad-hoc norms and on the basis of information provided by the firm and it has been observed by the committee that export product “Hexyl Salicylate” (Perfumery Compound) as applied by the firm appears to fall under para 4.11(b) of FTP, 2023, and the said para states that “For export of perfumes, perfumery compounds and various feeding redients containing vitamins, no authorisation shall be issued by Regional Authority under para 4.07 of HBP. The applicant firm is requested to clarify how this application comes under Para 4.07 of HBP, and the RA concerned is also directed to provide their comments on the same.	

Case No.	83 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	APOTHECARY PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004393AM25
RA File Number	31AX04000245 AM25
Licence No and Date	3111004133/28/11/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
FLORFENICOL Veterinary Oral Liquid 30% w/v	10000 Liters	1	FLORFENICOL (MIN. 98%)	3060 kg.

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

Case No.	84 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004398AM25
RA File Number	05AX04002902 AM25
Licence No and Date	0511029281/28/11/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Timolol Maleate Ophthalmic Solution, USP 0.25% (5 mL) (filling volume 5.3 ml in each number)	1 Number	1	Timolol Maleate USP	17.34 mg.
Timolol Maleate Ophthalmic Solution, USP 0.25% (10 mL) (filling volume 10.5 ml in each	1 Number	2	Timolol Maleate USP	34.68 mg.

number)				
Timolol Maleate Ophthalmic Solution, USP 0.5% (5 mL) (filling volume 5.3 ml in each number)	1 Number	3	Timolol Maleate USP	34.68 mg.
Timolol Maleate Ophthalmic Solution, USP 0.5% (10 mL) (filling volume 10.5 ml in each number)	1 Number	4	Timolol Maleate USP	69.36 mg.

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

Case No.	85 / NC/3/MEET/Jun/202526/5										
Case Status	Case Approved										
Party Name	JODAS EXPOIM PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025										
HQ File Number	HQRNORM APPLY 00004399AM25										
RA File Number	09AX04000703 AM25										
Licence No and Date	0911008500/28/11/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202122/15 dated 17/03/2022 against advance authorization No. 0911000062 dated 23/12/2020, 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:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Cefoperazone + Sulbactam powder for preparation for solution of intravenous and intramuscular administration 1g + 1g</td><td>1 Number</td><td>1</td><td>Cefoperazone Sodium and Sulbactam Sodium (1:1) Sterile</td><td>2.205 gram.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Cefoperazone + Sulbactam powder for preparation for solution of intravenous and intramuscular administration 1g + 1g	1 Number	1	Cefoperazone Sodium and Sulbactam Sodium (1:1) Sterile	2.205 gram.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Cefoperazone + Sulbactam powder for preparation for solution of intravenous and intramuscular administration 1g + 1g	1 Number	1	Cefoperazone Sodium and Sulbactam Sodium (1:1) Sterile	2.205 gram.							

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

Case No.	86 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004445AM25
RA File Number	03AX04004271 AM25
Licence No and Date	0311039180/29/11/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Copy of Master-Batch Formula showing net content of each input in the export, in each case.	

Case No.	87 / NC/3/MEET/Jun/202526/5			
Case Status	Case Approved			
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025			
HQ File Number	HQRNORM APPLY 00004448AM25			
RA File Number	05AX04002908 AM25			
Licence No and Date	0511029328/29/11/2024			
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 3411004545 dated 29/01/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Ciprofloxacin and Dexamethasone Sterile Otic Suspension 7.5ml ((Each ml contains Ciprofloxacin 3 mg. & Dexamethasone 1mg (Equivalent to 14625.000 Gm. Ciprofloxacin and 4875.000 Gm. Dexamethasone Bulk Drug))	1 Number	1	Ciprofloxacin	25.475 mg.
		2	Dexamethasone (Micronised)	7.65 mg.

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

Case No.	88 / NC/3/MEET/Jun/202526/5			
Case Status	Case Approved			
Party Name	VINCIT LABS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025			
HQ File Number	HQRNORM APPLY 00004500AM25			
RA File Number	05AX04002854 AM25			
Licence No and Date	0511029349/02/12/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No. 0511025080 dated 19/04/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Levofloxacin Hemihydrate	1 kg.	1	Levofloxacin Q Acid or Levofloxacin Carboxylic Acid	0.856 kg.
		2	N Methyl Piperazine	0.432 kg.

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

Case No.	89 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004512AM25
RA File Number	05AX04002899 AM25
Licence No and Date	0511029366/03/12/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202324/26 dated 22/03/2024 against advance authorization No. 0511023924 dated 13/02/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cefepime for Injection	1 Kg.	1	Cefepime HCL (Non Sterile)	0.655 kg.

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

Case No.	90 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004514AM25
RA File Number	05AX04002958 AM25
Licence No and Date	0511029369/03/12/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aug/202425/8 dated 28/08/2024 against advance authorization No. 0511025055 dated 19/04/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dorzolamide and Timolol Ophthalmic Solution, 2.0% w/v + 0.5%w/v, 5 ml Sterile Eye Drops ((Each ml contains Dorzolamide Hydrochloride equivalent to Dorzolamide 20 mg (Equivalent to 12.000Kg of Bulk Drug), and Timolol Maleate equivalent to Timolol 5.0 mg (Equivalent to 3.000 Kg. of Bulk Drug))	120000 Numbers	1	Dorzolamide Hydrochloride	14.051 kg.
		2	Timolol Maleate	4.284 kg.

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

Case No.	91 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004530AM25
RA File Number	34AX04000751 AM25
Licence No and Date	3411005757/04/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	92 / NC/3/MEET/Jun/202526/5										
Case Status	Case Approved										
Party Name	SENTISS PHARMA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025										
HQ File Number	HQRNORM APPLY 00004538AM25										
RA File Number	05AX04003000 AM25										
Licence No and Date	0511029403/04/12/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No. 0511023216 dated 11/01/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Inokain Eye Drops 0.4% 5 ml Vial (Each ml contains 4 mg of Benoxinate Hydrochloride)</td><td>1 Vial</td><td>1</td><td>Benoxinate HCL</td><td>20.4 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Inokain Eye Drops 0.4% 5 ml Vial (Each ml contains 4 mg of Benoxinate Hydrochloride)	1 Vial	1	Benoxinate HCL	20.4 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Inokain Eye Drops 0.4% 5 ml Vial (Each ml contains 4 mg of Benoxinate Hydrochloride)	1 Vial	1	Benoxinate HCL	20.4 mg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	93 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004574AM25
RA File Number	09AX04000714 AM25
Licence No and Date	0911008538/05/12/2024
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jul/202425/7 dated 06/08/2024 against advance authorization No. 0911003033 dated 20/05/2022, it was decided to fix ad-hoc norms under Para 4.07 of	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Colistimethate sodium powder for preparation of solution for inhalation 1000000 Units (each vial contains: Colistimethate sodium 1000000 Units)	120000 Numbers	1	Colistimethate Sodium	9.419 kg.

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

Case No.	94 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004588AM25
RA File Number	09AX04000820 AM25
Licence No and Date	0911008546/06/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	95 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	BRAWN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004589AM25
RA File Number	05AX04002984 AM25
Licence No and Date	0511029452/06/12/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tenoxicam Injection 20 mg / 2 ml Vial (Yellow Lyophilized Mass Filled In Clear Glass Vials)	1 Number	1	Tenoxicam BP (Yellow Crystalline Powder)	22 mg/Vial

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

Case No.	96 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	VACHICHEM INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004590AM25
RA File Number	07AX04001389 AM25
Licence No and Date	0711012984/06/12/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Sep/202425/9 dated 10/10/2024 against advance authorization No. 0711005637 dated 09/11/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
6-(2-Propeny)-Ergoline-8-Carboxylic Acid	1 kg.	1	Lysergol (9,10 Didehydro 6 Methyletergoline -8B-Methanol	2.98 kg.

CAS No. 81409-74-7			CAS No .602-85-7	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	97 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004593AM25
RA File Number	07AX04001402 AM25
Licence No and Date	0711012997/06/12/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No. 0711010591 dated 21/02/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Calcium Citrate Malate USP	1 kg.	1	Citric Acid	0.500 kg.
		2	DI-Malic Acid	0.477 kg.
		3	Calcium Carbonate	0.720 kg.

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

Case No.	98 / NC/3/MEET/Jun/202526/5
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Case Status	Case Deferred
Party Name	S KANT CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004594AM25
RA File Number	03AX04004339 AM25
Licence No and Date	0311039398/06/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	99 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004600AM25
RA File Number	09AX04000824 AM25
Licence No and Date	0911008548/06/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	100 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004615AM25
RA File Number	05AX04002962 AM25
Licence No and Date	0511029473/09/12/2024
Norms Committee Decision:	
The committee considered the request of firm for rfixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Which specific Dibasic Acid (Carbon Chain) is imported, if it is combination of various Dibasic Acid	

then percentage of each Dibasic Acid.

Case No.	101 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004621AM25
RA File Number	03AX04004517 AM25
Licence No and Date	0311039431/09/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	102 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004634AM25
RA File Number	09AX04000770 AM25
Licence No and Date	0911008566/09/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	103 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004636AM25
RA File Number	09AX04000736 AM25

Licence No and Date	0911008567/09/12/2024																		
Norms Committee Decision:																			
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0911007698 dated 06/08/2024, 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:-																			
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Aztreonam for Injection USP 1 Gram</td><td>1 Number</td><td>1</td><td>Aztreonam and Arginine</td><td>1.10 gm.</td></tr><tr><td>Aztreonam for Injection USP 500 mg</td><td>1 Number</td><td>2</td><td>Aztreonam and Arginine</td><td>0.55 gm.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Aztreonam for Injection USP 1 Gram	1 Number	1	Aztreonam and Arginine	1.10 gm.	Aztreonam for Injection USP 500 mg	1 Number	2	Aztreonam and Arginine	0.55 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Aztreonam for Injection USP 1 Gram	1 Number	1	Aztreonam and Arginine	1.10 gm.															
Aztreonam for Injection USP 500 mg	1 Number	2	Aztreonam and Arginine	0.55 gm.															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	104 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	MOREPEN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004639AM25
RA File Number	05AX04003091 AM25
Licence No and Date	0511029509/09/12/2024
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No.0511025590 dated 17/05/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
8-Chloro-6, 11-Dihydro -11(1-Methyl-4-Piperidinylidene)-5H benzo (5,6) Cyclohepta (1,2-B) Pyridine (LH09)	1 kg.	1	3-Chloro Benzyl Cyanide	1.37 kg.
		2	Sodium Methoxide	0.54 kg.
		3	Toluene	3.74 kg.
		4	N,N-Dimethyl Carbamoyl Chloride	0.68 kg.
		5	Methanol	0.47 kg.
		6	Tetrahydrofuran	2.41 kg.

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

Case No.	105 / NC/3/MEET/Jun/202526/5			
Case Status	Case Approved			
Party Name	FREESIA CHEMICALS			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025			
HQ File Number	HQRNORM APPLY 00004641AM25			
RA File Number	03AX04004323 AM25			
Licence No and Date	0311039458/09/12/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No. 0311029806 dated 01/01/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Cyclopentanone (CAS No. 120-92-3)	1 kg	1	Adipic Acid	1.93 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	106 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004643AM25
RA File Number	03AX04004331 AM25
Licence No and Date	0311039465/10/12/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202324/18 dated 17/03/2025 against advance authorization No. 0311028487 dated 04/11/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
N-Propyl Acetate	2000000 kg.	1	Acetic Acid (Glacial)	1218000 kg.
		2	N-Propanol	1210000 kg.

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

Case No.	107 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred

Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004650AM25
RA File Number	03AX04004531 AM25
Licence No and Date	0311039468/10/12/2024
Norms Committee Decision: The committee considered the request of firm for rfixation 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. Commercial value of Low Boiler and High Boiler. 2. Justification of low Yield i.e. 68%.	

Case No.	108 / NC/3/MEET/Jun/202526/5													
Case Status	Case Approved													
Party Name	JUBILANT GENERICS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025													
HQ File Number	HQRNORM APPLY 00004656AM25													
RA File Number	05AX04003055 AM25													
Licence No and Date	0511029526/10/12/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/5 dated 30/06/2025 against advance authorization No. 0511029526 dated 10/12/2024, 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Amantadine HCL Tablet 100 mg</td><td>1 Number</td><td>1</td><td>Amantadine Hydrochloride</td><td>102 mg/100 mg Tablet</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Amantadine HCL Tablet 100 mg	1 Number	1	Amantadine Hydrochloride	102 mg/100 mg Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Amantadine HCL Tablet 100 mg	1 Number	1	Amantadine Hydrochloride	102 mg/100 mg Tablet										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	109 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	CADCHEM LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004662AM25
RA File Number	30AX04000476 AM25
Licence No and Date	3011006185/10/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	110 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	SAPTAGIR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004668AM25
RA File Number	09AX04000826 AM25
Licence No and Date	0911008582/10/12/2024
Norms Committee Decision:	
The committee considered the request of firm for review/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:- Manufacturing Process in detail indicating Chemistry Molecular Weight and Percentage Yield	

Case No.	111 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	UNIMAX CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025

HQ File Number	HQRNORM APPLY 00004669AM25										
RA File Number	03AX04004566 AM25										
Licence No and Date	0311039500/10/12/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No.0311037957 dated 15/10/2024, 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>Azithromycin Dihydrate</td><td>1 kg.</td><td>1</td><td>Azithromycin Amine</td><td>0.9434 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Azithromycin Dihydrate	1 kg.	1	Azithromycin Amine	0.9434 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Azithromycin Dihydrate	1 kg.	1	Azithromycin Amine	0.9434 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	112 / NC/3/MEET/Jun/202526/5										
Case Status	Case Approved										
Party Name	MALIK LIFESCIENCES PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025										
HQ File Number	HQRNORM APPLY 00004671AM25										
RA File Number	05AX04002960 AM25										
Licence No and Date	0511029432/10/12/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No.0511028020 dated 22/10/2024, 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>Cefixime Tablets 200 mg (Each tablet</td><td>1 Number</td><td>1</td><td>Cefixime USP</td><td>204 mg/Tablet</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Cefixime Tablets 200 mg (Each tablet	1 Number	1	Cefixime USP	204 mg/Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Cefixime Tablets 200 mg (Each tablet	1 Number	1	Cefixime USP	204 mg/Tablet							

contains Cefixime USP (as Trihydrate equivalent to Cefixime 200 mg on anhydrous basis))			(as Trihydrate)	
Cefixime Tablets 100 mg (Each tablet contains Cefixime USP (as Trihydrate equivalent to Cefixime 100 mg on anhydrous basis))	1 Number	2	Cefixime USP (as Trihydrate)	102 mg/Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	113 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004678AM25
RA File Number	03AX04004547 AM25
Licence No and Date	0311039510/11/12/2024
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product '<i>Galaxmusk Pure</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. Such products are mandatorily required to be processed under Para 4.06 of the HBP. The Committee provided the firm an opportunity for a Personal Hearing on 24.06.2025 in case of other authorization for same export product to clarify and establish that the product '<i>Galaxmusk Pure</i>' does not fall under the said restricted category . During the Personal Hearing, the firm failed to provide a satisfactory explanation or furnish credible supporting evidence to demonstrate that the product in question does not fall under the category of perfume or perfumery compound as defined in Para 4.11(b) of the FTP. Accordingly, after due consideration of the facts of the case, the submissions made, and the relevant provisions of the FTP and HBP, the Committee has decided as under:	

The request for fixation of norms under Para 4.07 of the HBP for the product ‘Galaxmusk Pure’ is hereby rejected and the RA shall ensure that the authorisation is regularized by payment of applicable Customs duty and interest.

Case No.	114 / NC/3/MEET/Jun/202526/5										
Case Status	Case Approved										
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025										
HQ File Number	HQRNORM APPLY 00004680AM25										
RA File Number	03AX04004595 AM25										
Licence No and Date	0311039513/11/12/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No.0311037957 dated 15/10/2024, 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>Artemether</td><td>1 kg.</td><td>1</td><td>Artemisinin</td><td>1.04 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Artemether	1 kg.	1	Artemisinin	1.04 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Artemether	1 kg.	1	Artemisinin	1.04 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	115 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004695AM25
RA File Number	05AX04002980 AM25
Licence No and	0511029585/12/12/2024

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0511025589 dated 17/05/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed
Di-Ethyl Maleate (DEM)	1 Kg.	1	Maleic Anhydride	0.67 Kg.
		2	Denatured Ethyl Alcohol	0.65 Kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	116 / NC/3/MEET/Jun/202526/5			
Case Status	Case Approved			
Party Name	DIVI'S LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025			
HQ File Number	HQRNORM APPLY 00004696AM25			
RA File Number	09AX04000834 AM25			
Licence No and Date	0911008583/12/12/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0911007722 dated 09/08/2024, 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.
Iopamidol (Powder)	1 kg.	1	Atipa Di Chloride (Solid)	1.27 kg.

		2	Dimethyl Formamide (Liquid)	0.68 kg.
		3	N N Dimethyl Acetamide (Liquid)	1.46 kg.
		4	Nitromethane (Liquid)	0.48 kg.
		5	L Lactic Acid (Solid)	0.67 kg.

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

Case No.	117 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	ANNORA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004700AM25
RA File Number	09AX04000833 AM25
Licence No and Date	0911008599/12/12/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0911007832 dated 29/08/2024, 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.
Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution 17.5g/3.13g / 1.6 g per 6 Ounce, ((Each 6-ounce bottle contains,Sodium Sulfate	1 Number Bottle	1	Sodium Sulfate USP(Sodium sulphates: Disodium sulphate)	17.85 gm.
		2	Potassium Sulfate (Sulphates;	3.193 gm.

USP 17.5 g Potassium Sulfate 3.13 g Magnesium Sulfate USP 1.6g))			Alums; Peroxosulphates (Persulphates) - Other)	
		3	Magnesium Sulfate USP (Other sulphates: of magnesium)	1.632 gm.

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

Case No.	118 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004702AM25
RA File Number	03AX04004563 AM25
Licence No and Date	0311039546/12/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	119 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004747AM25
RA File Number	03AX04004578 AM25
Licence No and Date	0311039577/13/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	120 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004784AM25
RA File Number	03AX04004537 AM25
Licence No and Date	0311039639/16/12/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0311030266 dated 18/01/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Fenofibrate 145mg tablets) (68785000 Nos) (Net Content:1) 10073.426 KGS 2) 10013.032 KGS 3) (Indi):2031.909 KGS 4) (Indi):198.789 KGS 5) (Indi):691.289 KGS 6) (Indi):8985.385 KGS 7) (Indi):5857.043 KGS 8) (Indi):5136.864 KGS9) (Indi): 61.907 KGS 10) (Indi): 2042.56 KGS)	1 Number	1	Fenofibrate Micronized IH/Ph Eur	147.90 mg.
		2	Sucrose PH.Eur (exepient)	146.45 mg.

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

Case No.	121 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004814AM25
RA File Number	03AX04004624 AM25
Licence No and Date	0311039663/16/12/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Drug Manufacturing License for the export item. 2. Complete and Balanced Chemical reactions, with Molecular Weight and percentage yield on molar basis. 3. Copy of Certificate of Analysis (CoA) of export item.	

Case No.	122 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004815AM25
RA File Number	03AX04004626 AM25
Licence No and Date	0311039664/16/12/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. Copy of Drug Manufacturing License for the export item. II. Complete and Balanced Chemical reactions, with Molecular Weight and percentage yield on molar basis. III. Copy of Certificate of Analysis (CoA) of export item.	

Case No.	123 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004830AM25
RA File Number	03AX04004728 AM25
Licence No and Date	0311039683/17/12/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0311033874 dated 15/05/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50 mg) 50 ml vial	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50 mg) 100 ml via	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50 mg) 250 ml vial	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50 mg) 500 ml vial	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100 mg) 50 ml vial	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100 mg) 100 ml vial	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial

Ashoxy 10% (Oxytetracycline Injection 100 mg) 250 ml vial	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial
PAN Ashoxy 3% (Oxytetracycline Injection 30 mg) 100 ml vial	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200 mg) 50 ml vial	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200 mg) 100 ml vial	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200 mg) 250 ml vial	1 Number	11	PROPYLENE GLYCOL	45.00 gm.Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 10ml vial	1 Number	12	PROPYLENE GLYCOL	10.40 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 50 ml vial	1 Number	13	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 100ml vial	1 Number	14	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 250 ml vial	1 Number	15	PROPYLENE GLYCOL	260.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 500 ml vial	1 Number	16	PROPYLENE GLYCOL	520.00 gm/Vial
Ashiver Forte (Ivermectin 10 mg and Clorsulon 100 mg Injection) 50 ml vial	1 Number	17	PROPYLENE GLYCOL	50.96 gm/Vial
Ashiver Forte (Ivermectin 10 mg and Clorsulon 100 mg Injection) 100 ml vial	1 Number	18	PROPYLENE GLYCOL	101.92 gm/Vial
Ashienro 10% (Enrofloxacin	1 Number	19	PROPYLENE GLYCOL	5.20 gm/Vial

Injection 100 mg) 50 ml vial				
Ashienro 10% (Enrofloxacin Injection 100 mg) 100 ml vial	1 Number	20	PROPYLENE GLYCOL	10.40 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100 mg) 250 ml vial	1 Number	21	PROPYLENE GLYCOL	26.00 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200 mg) 50 ml vial	1 Number	22	PROPYLENE GLYCOL	10.40 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200 mg) 100 ml vial	1 Number	23	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200 mg) 250 ml vial	1 Number	24	PROPYLENE GLYCOL	52.00 gm/Vial
Ashityl 5% (Tylosin Tartrate injection eq to Tylosin 50 mg) 50 ml vial	1 Number	25	PROPYLENE GLYCOL	10.40 gm/Vial
Ashital 10% (Closantel 10% Inj) 100 ml vial	1 Number	26	PROPYLENE GLYCOL	55.12 gm/Vial
RA concerned may take further necessary action as per above decision of NC.				

Case No.	124 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004840AM25
RA File Number	03AX04004600 AM25
Licence No and	0311039713/17/12/2024

Date	
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. Copy of Drug Manufacturing License for the export item. 2. Complete and Balanced Chemical reactions, with Molecular Weight and percentage yield on molar basis. 3. Copy of Certificate of Analysis (CoA) of export item.	

Case No.	125 / NC/3/MEET/Jun/202526/5										
Case Status	Case Approved										
Party Name	HEMA DYECHEM PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025										
HQ File Number	HQRNORM APPLY 00004850AM25										
RA File Number	52AX04000282 AM25										
Licence No and Date	5211011126/17/12/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. Allowed.</th></tr><tr><td>4 Chloro 2-5 Dimethoxy Aniline</td><td>1 kg.</td><td>1</td><td>Para Dimethoxy Benzene</td><td>0.982 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.	4 Chloro 2-5 Dimethoxy Aniline	1 kg.	1	Para Dimethoxy Benzene	0.982 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.							
4 Chloro 2-5 Dimethoxy Aniline	1 kg.	1	Para Dimethoxy Benzene	0.982 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	126 / NC/3/MEET/Jun/202526/5			
Case Status	Case Approved			
Party Name	COVALENT LABORATORIES PRIVATE LIMITED			
Meeting Number	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025			

and Date	
HQ File Number	HQRNORM APPLY 00004856AM25
RA File Number	09AX04000854 AM25
Licence No and Date	0911008628/17/12/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0911007730 dated 13/08/2024, 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.
7-AMINO-3-VINYL-3-CEPHEM-4-CARBOXYLIC ACID (7-AVCA) (API)	1 kg.	1	7-Phenylacetamideo-3-Chloromethyl Cephalosporonic Acid Para Methoxybenzyl Ester (GCLE)	2.672 kg.
		2	Acetone	8.85 kg.
		3	Methylene Chloride	5.70 kg.
		4	Methanol	5.70 kg.
		5	Activated Carbon	0.100 kg.
		6	Triphenyl Phosphine	1.26 kg.

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

Case No.	127 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025

HQ File Number	HQRNORM APPLY 00004857AM25
RA File Number	09AX04000845 AM25
Licence No and Date	0911008629/17/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	128 / NC/3/MEET/Jun/202526/5													
Case Status	Case Approved													
Party Name	HEMA DYECHEM PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025													
HQ File Number	HQRNORM APPLY 00004868AM25													
RA File Number	03AX04004730 AM25													
Licence No and Date	0311039736/18/12/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. Allowed.</th></tr><tr><td>4 Chloro 2-5 Dimethoxy Aniline</td><td>1 Kg.</td><td>1</td><td>Para Dimethoxy Benzene</td><td>0.982 Kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.	4 Chloro 2-5 Dimethoxy Aniline	1 Kg.	1	Para Dimethoxy Benzene	0.982 Kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.										
4 Chloro 2-5 Dimethoxy Aniline	1 Kg.	1	Para Dimethoxy Benzene	0.982 Kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	129 / NC/3/MEET/Jun/202526/5			
Case Status	Case Deferred			
Party Name	JUBILANT INGREVIA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025			
HQ File Number	HQRNORM APPLY 00004895AM25			
RA File Number	05AX04003211 AM25			

Licence No and Date	0511029723/19/12/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. To give balance chemical reaction indicating molecular weight of all the reactants and product with stage wise yield of the reaction/ 2. Process flow charts indicating where Alumino Silicate Catalyst, Denatured Ethyl Alcohol and Methanol are used in the chemical reaction giving their application/use. 3. Calculation of the requirement of all the chemicals with justification of low yield.	

Case No.	130 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004896AM25
RA File Number	03AX04004760 AM25
Licence No and Date	0311039753/19/12/2024
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	131 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	KLJ PETROPLAST LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004898AM25
RA File Number	05AX04003186 AM25
Licence No and Date	0511029729/19/12/2024
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against DGFT (HQ)	

File No.NORMREVIW00006341AM25, 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)	1 kg.	1	Phthalic Anhydride	0.700 kg.
		2	Denatured Ethyl Alcohol	0.435 kg.

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

Case No.	132 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004922AM25
RA File Number	09AX04000851 AM25
Licence No and Date	0911008669/20/12/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	133 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004923AM25
RA File Number	09AX04000869 AM25
Licence No and Date	0911008670/20/12/2024
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Bupropion Hydrochloride	1 kg.	1	3 Chloropropiophenone	0.85 kg.

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

Case No.	134 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	DCM NOUVELLE SPECIALTY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004925AM25
RA File Number	05AX04003062 AM25
Licence No and Date	0511029764/20/12/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.
Dibenzylamine	1 kg.	1	Benzonitrile	0.6972 kg.

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

Case No.	135 / NC/3/MEET/Jun/202526/5
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Case Status	Case Approved										
Party Name	DCM NOUVELLE SPECIALTY CHEMICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025										
HQ File Number	HQRNORM APPLY 00004926AM25										
RA File Number	05AX04003061 AM25										
Licence No and Date	0511029765/20/12/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. Allowed.</th></tr><tr><td>Dibenzylamine</td><td>1 kg.</td><td>1</td><td>Benzonitrile</td><td>0.6972 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.	Dibenzylamine	1 kg.	1	Benzonitrile	0.6972 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.							
Dibenzylamine	1 kg.	1	Benzonitrile	0.6972 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	136 / NC/3/MEET/Jun/202526/5
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004930AM25
RA File Number	03AX04004652 AM25
Licence No and Date	0311039796/20/12/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- - Copy of Drug Manufacturing License for the export item. - Complete and Balanced Chemical reactions, with Molecular Weight and percentage yield on molar basis. - Copy of Certificate of Analysis (CoA) of export item.	

Case No.	137 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004931AM25
RA File Number	03AX04004696 AM25
Licence No and Date	0311039799/20/12/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxycycline Tablets, USP 50 MG 100 S ((21,600 Bottles X 100 Per Bottles = 21,60,000 Tablets) (Total Weight of Export Product = 108.000 Kgs) (Exempts imported input/material weight inclusive of wastage = 116.327 Kgs))	1 Number	1	Doxycycline USP (Monohydrate)	53.066 mg.
Doxycycline Tablets, USP 75 MG 100 S ((2,200 Bottles X 100 Per Bottles = 2,20,000 Tablets) (Total Weight of Export Product = 16.500 Kgs) (Exempts imported input/material weight inclusive of wastage = 17.772 Kgs))	1 Number	2	Doxycycline USP (Monohydrate)	79.600 mg.
Doxycycline Tablets, USP 100 MG 500 S ((9,800 Bottles X 500 Per Bottles = 49.00.000 Tablets) (Total Weight of Export Product = 490.000 Kgs) (Exempts imported input/material weight inclusive of wastage = 527.779 Kgs))	1 Number	3	Doxycycline USP (Monohydrate)	106.13 mg.

Doxycycline Tablets, USP 100 MG 50 S ((98,000 Bottles X 50 Per Bottles = 49,00,000 Tablets) (Total Weight of Export Product = 490.000 Kgs) (Exempts imported input/material weight inclusive of wastage = 527.779 Kgs))	1 Number	4	Doxycycline USP (Monohydrate)	106.13 mg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	138 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	LEE PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004945AM25
RA File Number	09AX04000848 AM25
Licence No and Date	0911008676/20/12/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Rosuvastatin Calcium	1 kg.	1	Tert.Butyl-(E)-(6[-[4-(4-fluorophenyl)-6-isopropyl-2-(N-methyl Sulfonyl)amino]pyrimidin-5-yl]vinyl](4R,6S)-2,2- Dimethy (tert-Butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methyl methyl sulfonamido) pyrimidin-5-yl) vinyl)-2,2-dimethyl-1,3-Dioxin -4-yl) acetate)	1.30 kg.

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

Case No.	139 / NC/3/MEET/Jun/202526/5
Case Status	Case Approved
Party Name	LEE PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202526/ 5 and 30/06/2025
HQ File Number	HQRNORM APPLY 00004946AM25
RA File Number	09AX04000850 AM25
Licence No and Date	0911008677/20/12/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Voriconazole	1 kg.	1	4-chloro-6-ethyl-5-fluoropyrimidine	3.30 kg.
		2	Tetrahydrofuran	20.50 kg.
		3	R Camphorsulphonic Acid(L-(-)-Camphorsulfonic Acid)	1.01 kg.

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