



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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

Minutes of the Norms Committee-3 Meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 (actually held on 08/04/2026) under the Chairmanship of Shri Rakesh Kumar, Addl. DGFT for considering the cases/issues under Duty Exemption Scheme (Chapter-4) of the Foreign Trade Policy, 2023 pertaining to Chemical and Allied products falling under Chapter 29 and 30.

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

Sl. No.	Name & Designation	Department
1	Shri Dinesh Narain Mathur, Technical Expert	Consultant (Pharma)
2	Shri Shaish Kumar, Technical Expert	Consultant (Chemical)
3	Shri Nand	Consultant

	Lal	(Chemical)
4	Shri Raman Kumar, Joint DGFT	DGFT (HQ)
5	Smt. Skina Rani, FTDO	DGFT (HQ)

3. The Norms Committee has taken decisions 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 regularisation of the case.

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

5. RAs shall also ensure that authorization is issued or redeemed based on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less. In this regard, full compliance with the provisions of Para 4.12 of FTP, Para 4.16, Para 4.21, and Para 4.51 of HBP shall be made.

Case No.	1 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	B G P HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00004745AM26
RA File Number	NA
Licence No and Date	NA

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Nicotine Polacrilex (Contains 20% Nicotine)	1 kg.	1	ION EXCHANGE RESIN	0.852 kg.

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

Case No.	2 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00005879AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the cases as per the agenda. The representatives of the firm attended the Personal Hearing through Video Conference (VC) wherein Technical Expert of the Department of Bio-Technology was also present through VC. The representative of the firm explained the reason for fixation of ad-hoc norms filed under para 4.06 of HBP. The Committee heard the explanation of the firm and after due deliberation with the Technical Expert of Deptt. of Bio-Technology decided to submit the following documents as sought by DBT during hearing from the firm:- 1. Batch Production Record. 2. Calculation Sheet of Bulk Antigen. 3. Certificate of Analysis (CoA). 4. General Control Record.	

Case No.	3 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	JAGSON PAL PHARMACEUTICALS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00005861AM26
RA File Number	052304000165 AM16
Licence No and Date	0510395004/20/07/2015
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from	

the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Mifepristone Tablets 200 mg.	1 Number	1	Mifepristone (USDMF Grade) (API)	204.0 mg.
Misoprostol Tablets 200 mcg.	1 Number	2	Misoprostol Dispersion(API)	204.0 mcg.

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

Case No.	4 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	SIRMAXO CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00004150AM26
RA File Number	039504000492 AM17
Licence No and Date	0310809770/13/12/2016
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the norms earlier ratified done as per Drug Manufacturing Licence with 2% wastage. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	5 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026

HQ File Number	HQRNORM REVIW00005522AM26
RA File Number	039404000726 AM18
Licence No and Date	0310817755/13/12/2017
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix-4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Copy of Master Batch Formula for each export item.	

Case No.	6 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	HALEOS LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00002911AM26
RA File Number	092404000654 AM18
Licence No and Date	0910066137/12/04/2018
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	7 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	SIRMAXO CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00004149AM26
RA File Number	039504000221 AM19
Licence No and Date	0310821782/20/06/2018
Norms Committee Decision:	

The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the norms had earlier been ratified on the basis of the Drug Manufacturing Licence with permissible wastage of 2%. Accordingly, the Committee did not find any justification for revising the existing norms and decided to reject the request, thereby maintaining the status quo.

Case No.	8 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00003165AM26
RA File Number	039404000312 AM19
Licence No and Date	0310822337/17/07/2018
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	9 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	HALEOS LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00002912AM26
RA File Number	092404000205 AM19
Licence No and Date	0910066505/24/07/2018
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	10 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00003500AM26
RA File Number	092404000369 AM19
Licence No and Date	0910066835/13/11/2018
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	11 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00003166AM26
RA File Number	039404000744 AM19
Licence No and Date	0310825255/28/11/2018
Norms Committee Decision:	
The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	12 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	VENOR PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00002542AM26
RA File Number	612404000020 AM19
Licence No and Date	6110001570/13/12/2018

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Injection Levobupivacaine HCL 5 mg/ml, 10 ml Ampoule	1 Number	1	Levobupivacaine HCL	55.00 mg.

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

Case No.	13 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00003501AM26
RA File Number	092404000534 AM19
Licence No and Date	0910067129/04/02/2019
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	14 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	INDO AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00002408AM26
RA File Number	039404000984 AM19
Licence No and Date	0310827206/21/02/2019
Norms Committee Decision:	

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
C12-C14 AMINE PURE	1 kg.	1	CRUDE COCO AMINE (C12-C14 AMINE CRUDE)	1.055 kg.

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

Case No.	15 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00004917AM26
RA File Number	039404000496 AM20
Licence No and Date	0310831890/27/09/2019

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Triamcinolone IP/EP/BP/USP	1 kg.	1	3,20-Dioxopregna-1,4,9(11),16 - Tetraen - 21- Ylacetate (3 TR)	1.15 kg.

Triamcinolone Acetonide IP/EP/BP/USP	1 kg.	2	3,20-Dioxopregna-1,4,9(11),16 - Tetraen - 21- Ylacetate (3 TR)	1.05 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	16 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00005976AM26
RA File Number	052404000616 AM20
Licence No and Date	0510413195/03/01/2020
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	17 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00005021AM26
RA File Number	318304000150 AM20
Licence No and Date	3110067697/25/02/2020
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix-4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents:	

1. To give complete chemistry giving molecular weight of both reactants and products indicating yield of the reaction.
2. Based on yield of the reaction, to give calculation of requirement of raw material.

Case No.	18 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00006119AM26
RA File Number	092404000036 AM21
Licence No and Date	0910068668/24/04/2020

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PLENISH-K 600 SR TABLETS	36,000,000 Numbers	1	NACOL 18-98 P (Stearyl Alcohol)	2160.0 kg.
		2	Ethanol Absolute (Ethanol Anhydrous)	2502.0 kg.

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

Case No.	19 / NC/3/MEET/Apr/202627/1
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Case Status	Case Approved
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVW00006021AM26
RA File Number	092404000632 AM20
Licence No and Date	0910068801/26/05/2020

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/2022/4 dated 12/02/2021 against advance authorization No. 0910068698 dated 29/04/2020, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Bolt Energy Effervescent Tablets; (Each Tablet Contains- Glucuronolactone 50 mg, Ascorbic Acid 300 mg, Caffeine 50 mg.	1 Number Tablet	1	Glucuronolactone	51.00 mg
		2	Ascorbic Acid (Crystalline)	306.0 mg
		3	Caffeine Anhydrous	51.00 mg.
		4	Sodium Polyphosphate	50.0 mg.
		5	Sodium Hydrogen Carbonate	950. mg.
		6	Gin Fizz Micron Flavour	30.0 mg.
		7	Macrogol 6000	135.00 mg.
		8	Monosodium Fumarate	2000.00 mg.

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

Case No.	20 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00006048AM26
RA File Number	092404000605 AM20
Licence No and Date	0910068804/27/05/2020
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	21 / NC/3/MEET/Apr/202627/1										
Case Status	Case Approved										
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026										
HQ File Number	HQRNORM REVIW00002715AM26										
RA File Number	039404000210 AM21										
Licence No and Date	0310836960/30/06/2020										
Norms Committee Decision:											
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Secnidazole Taste Masked Pellets</td><td>1 kg.</td><td>1</td><td>Secnidazole IH</td><td>478.235 gm.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Secnidazole Taste Masked Pellets	1 kg.	1	Secnidazole IH	478.235 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Secnidazole Taste Masked Pellets	1 kg.	1	Secnidazole IH	478.235 gm.							
RA concerned may take further necessary action as per above decision of NC-III.											

Case No.	22 / NC/3/MEET/Apr/202627/1													
Case Status	Case Approved													
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026													
HQ File Number	HQRNORM REVIW00002716AM26													
RA File Number	039404000210 AM21													
Licence No and Date	0310836960/30/06/2020													
Norms Committee Decision:														
The Committee examined the request of the firm for the fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Secnidazole Taste Masked Pellets</td><td>1 kg.</td><td>1</td><td>Secnidazole IH</td><td>478.235 gm.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Secnidazole Taste Masked Pellets	1 kg.	1	Secnidazole IH	478.235 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Secnidazole Taste Masked Pellets	1 kg.	1	Secnidazole IH	478.235 gm.										
RA concerned may take further necessary action as per above decision of NC-III.														

Case No.	23 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	SAVLA CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00004374AM26
RA File Number	039504000192 AM21
Licence No and Date	0310837078/08/07/2020
Norms Committee Decision:	
The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the	

following documents:-

1. Copy of Bill of Entries

Case No.	24 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	KOSHA CHEMTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00005966AM26
RA File Number	039404000306 AM21
Licence No and Date	0310837580/10/08/2020
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	25 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00005625AM26
RA File Number	03AA04014068 AM21
Licence No and Date	0311000348/22/12/2020
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Secnidazole Taste Masked Pellets	1 kg.	1	Secnidazole IH	478.235 gm.
Secnidazole 2 gm. Sachets (Secnizol)	1 Number	2	Secnidazole IH	2.02 gm.
Secnidazole 2 gm. Sachets (Tribactin 2 gm. Sachets)	1 Number	3	Secnidazole IH	2.02 gm.

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

Case No.	26 / NC/3/MEET/Apr/202627/1													
Case Status	Case Approved													
Party Name	BHAGWATI INDUSTRIES													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026													
HQ File Number	HQRNORM REVIW00006055AM26													
RA File Number	08AA04001833 AM22													
Licence No and Date	0811001364/29/04/2021													
Norms Committee Decision:														
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-														
<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">Chloral Anhydrous</td><td rowspan="2">1 kg.</td><td>1</td><td>Ethyl Alcohol</td><td>0.65 kg.</td></tr><tr><td>2</td><td>Caustic Soda</td><td>0.40 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Chloral Anhydrous	1 kg.	1	Ethyl Alcohol	0.65 kg.	2	Caustic Soda	0.40 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Chloral Anhydrous	1 kg.	1	Ethyl Alcohol	0.65 kg.										
		2	Caustic Soda	0.40 kg.										

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

Case No.	27 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00002372AM26
RA File Number	03AA04019330 AM22
Licence No and Date	0311004745/19/06/2021

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. 0511024949 dated 10/04/2024 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.
Meropenem Sodium Sterile (Meropenem for Injection)	1 kg.	1	Meropenem Trihydrate (Non Sterile)	0.8968 kg.
		2	Packing Material	Relevant as per Packing Policy & General Notes.

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

Case No.	28 / NC/3/MEET/Apr/202627/1
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Case Status	Case Rejected
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00003189AM26
RA File Number	03AA04033537 AM22
Licence No and Date	0311005080/02/07/2021
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm has requested to add additional item of export and import, however, the firm has not submitted the amended license for additional items. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	29 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	METROPOLITAN EXIMCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00005332AM26
RA File Number	03AA040108347 AM22
Licence No and Date	0311007901/25/10/2021
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	30 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ARKRAY HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00003329AM26
RA File Number	52AA04018127 AM22
Licence No and Date	5211001587/18/11/2021

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PARAHIT-F DEVICE TEST KIT([1 KIT = 50 TESTS OR 25 TESTS OR 10 TESTS] [RAPID DIAGNOSTICS TEST KIT])	12502500 Numbers	1	Anti Mouse Ig G [Goat])	10.863 gram
		2	Mab to P. Falciparum For NCM/Malaria K	3.647 gram
		3	Mab to P. Falciparum Colloidal Gold Reagent	1.711 gram
		4	Mouse Ig G Purified	0.856 gram
		5	Conjugate Releasing Pad Gr 6615-21 MM X 500 FT- Parah)	167811 Feet
		6	Conjugated Releasing Pad 10 mm Grade 6615)	167811 Feet
		7	Sample Pad Grade 238 Size 12 mm X 100 m	55567 Meter
		8	Absorbent Pad for Rapid Test 22 Mm X 50 mtr-CF5	55567 Meter
		9	Dis Seafty Seal Lancets [Pack of 25] & [Pack of 10])	1,25,02,500 Numbers

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

Case No.	31 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	LAZERHEAD LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00004743AM26
RA File Number	09AA04012424 AM22
Licence No and Date	0911001950/26/11/2021
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	32 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	PMC RUBBER CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00006034AM26
RA File Number	02AA04035173 AM22
Licence No and Date	0211001583/02/12/2021
Norms Committee Decision:	
The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	33 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00004845AM26
RA File Number	05AX04000761 AM23
Licence No and Date	0511013170/13/06/2022
Norms Committee Decision:	

The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.

Case No.	34 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00006693AM26
RA File Number	05AX04000760 AM23
Licence No and Date	0511013171/13/06/2022
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the norms had earlier been ratified on the basis of the Drug Manufacturing Licence with permissible wastage of 2%. Accordingly, the Committee did not find any justification for revising the existing norms and decided to reject the request, thereby maintaining the status quo.	

Case No.	35 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00005941AM26
RA File Number	03AX04001157 AM23
Licence No and Date	0311015490/14/06/2022
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the norms had earlier been ratified on the basis of the Drug Manufacturing Licence with permissible wastage of 2%. Accordingly, the Committee did not find any justification for revising the existing norms and decided to reject the request, thereby maintaining the status quo.	

Case No.	36 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00005722AM25
RA File Number	03AX04002261 AM23
Licence No and Date	0311016368/15/07/2022
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix-4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Chemical reaction indicating molecular weight of both reactant and the products with yield of the reaction. 2. Stoichiometric material balance on a molar basis and to give value of by-product Methanol obtained during the reaction. 3. Concentration of the ammonia in aqueous solution and accordingly, calculation of requirement of both the chemical	

Case No.	37 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00002375AM26
RA File Number	03AX04002208 AM23
Licence No and Date	0311016558/25/07/2022
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	38 / NC/3/MEET/Apr/202627/1													
Case Status	Case Approved													
Party Name	PRACHEM LABORATORIES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026													
HQ File Number	HQRNORM REVIW00002184AM26													
RA File Number	08AX04000754 AM23													
Licence No and Date	0811005702/08/08/2022													
Norms Committee Decision:														
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Triamcinolone Acetonide BP/EP/USP((9?-Fluoro-11?,21-dihydroxy-16?,17-isopropylidenedioxy-1,4-pregnadiene-3,20-dione))</td><td>1 kg.</td><td>1</td><td>3TR (Tetraene Acetate) (21-(Acetyloxy)-Pregna-1,4,9(11),16 Tetraene-3,20-Dione)</td><td>1.05 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Triamcinolone Acetonide BP/EP/USP((9?-Fluoro-11?,21-dihydroxy-16?,17-isopropylidenedioxy-1,4-pregnadiene-3,20-dione))	1 kg.	1	3TR (Tetraene Acetate) (21-(Acetyloxy)-Pregna-1,4,9(11),16 Tetraene-3,20-Dione)	1.05 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Triamcinolone Acetonide BP/EP/USP((9?-Fluoro-11?,21-dihydroxy-16?,17-isopropylidenedioxy-1,4-pregnadiene-3,20-dione))	1 kg.	1	3TR (Tetraene Acetate) (21-(Acetyloxy)-Pregna-1,4,9(11),16 Tetraene-3,20-Dione)	1.05 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	39 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00002872AM26
RA File Number	03AX04002399 AM23
Licence No and Date	0311017082/10/08/2022
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	40 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00003195AM26
RA File Number	03AX04002728 AM23
Licence No and Date	0311017256/16/08/2022
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm has requested to add additional items of export and import; however, the firm has not submitted the amended license for additional items. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	41 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00002377AM26
RA File Number	03AX04003060 AM23
Licence No and Date	0311018071/22/09/2022
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	42 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026

and Date	
HQ File Number	HQRNORM REVIW00004847AM26
RA File Number	05AX04002651 AM23
Licence No and Date	0511016260/08/12/2022
Norms Committee Decision: The committee considered the case as per the agenda, and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix-4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided that the firm may be advised to explain the details given in Appendix-4E and Appendix-4K with a copy of the Drug Manufacturing Licence.	

Case No.	43 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00005825AM23
RA File Number	05AX04003069 AM23
Licence No and Date	0511016941/19/01/2023
Norms Committee Decision: The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the firm was advised submit the following information/documents:- I. To give proper Chemical reaction starting clearly from import items asked for, in the license, giving molecular weight and name of the chemicals and also yield of the reaction. II. Function/application of each raw material asked for in the process indicating raw material, catalyst solvent/diluents, etc., as the case may be, giving Stoichiometric material balance on a molar basis. III. Value of by-product, if any and with End use of export item.	

Case No.	44 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	AGRO SOLVENT PRODUCTS PVT LTD

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001107AM24
RA File Number	56AX04000449 AM23
Licence No and Date	5611001909/25/05/2023
Norms Committee Decision: The firm was called for a Personal Hearing on 08.04.2026 through Video Conference, but the firm could not appear before the Norms Committee because of a medical condition. It was decided to grant one more opportunity to the firm for a <u>Personal Hearing</u> with relevant documents/information.	

Case No.	45 / NC/3/MEET/Apr/202627/1																
Case Status	Case Approved																
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026																
HQ File Number	HQRNORM APPLY 00004957AM24																
RA File Number	03AX04002106 AM24																
Licence No and Date	0311026174/09/08/2023																
Norms Committee Decision:																	
The Committee examined the request of the firm for fixation of ad-hoc norms . After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below.:-																	
<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">Sodium Chloride 0.9% 50 ml (AUS)</td><td rowspan="3">1 Number</td><td>1</td><td>Sodium Chloride (SANAL) (EP)</td><td>0.4725 gm.</td></tr><tr><td>6</td><td>BOP Infusion (Art.No 0434171)</td><td>Net content in export + 1% wastage.</td></tr><tr><td>11</td><td>BOP Injection (Art. 0434481)</td><td>Net content in export + 1% wastage.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sodium Chloride 0.9% 50 ml (AUS)	1 Number	1	Sodium Chloride (SANAL) (EP)	0.4725 gm.	6	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.	11	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Sodium Chloride 0.9% 50 ml (AUS)	1 Number	1	Sodium Chloride (SANAL) (EP)	0.4725 gm.													
		6	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.													
		11	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.													

		16	SSC Infusion (0434181)	Net content in export + 1% wastage.
		21	SSC Injection (Art. 0434371)	Net content in export + 1% wastage.
		26	SF9-11 195/95 Prim.film (0369581) 50 and 100 ml	Net content in export + 1% wastage.
		31	OFR2-11 150/524 for 50 and 100 ml (0369701)	Net content in export + 1% wastage.
		36	UFR2-11 150/524-50ml to 1000 (0369661)	Net content in export + 1% wastage.
		41	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
Sodium Chloride 0.9 % 100 ml (AUS)	1 Number	2	Sodium Chloride (SANAL) (EP)	0.945 gm.
		7	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		12	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		17	SSC Infusion (0434181)	Net content in export + 1% wastage.
		22	SSC Injection (Art. 0434371)	Net content in export + 1% wastage.

		27	SF9-11 195/95 Prim.film (0369581) 50 and 100 ml	Net content in export + 1% wastage.
		32	OFR2-11 150/524 for 50 and 100 ml (0369701)	Net content in export + 1% wastage.
		37	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
		42	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
Sodium Chloride 0.9% 250 ml (AUS)	1 Number	3	Sodium Chloride (SANAL) (EP)	2.3625 gm.
		8	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		13	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		18	SSC Infusion (0434181)	Net content in export + 1% wastage.
		23	SSC Injection (Art. 0434371)	Net content in export + 1% wastage.
		28	SF9-11 195/100 Prim. Film (Art.0369591)	Net content in export + 1% wastage.
		33	OFR2-11 150/524 for 50 and 100 ml (0369701)	Net content in export + 1% wastage.

Sodium Chloride 0.9% 500 ml (AUS)	1 Number	38	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
		43	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
		4	Sodium Chloride (SANAL) (EP)	4.725 gm.
		9	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		14	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		19	SSC Infusion (0434181)	Net content in export + 1% wastage.
		24	SSC Injection(Art. 0434371)	Net content in export + 1% wastage.
		29	SF9-11 195/135 Prim film Art. 0369621) 500 ml	Net content in export + 1% wastage.
		34	OFR2-11 120/524-500ml and 1000 ml (0369681)	Net content in export + 1% wastage.
		39	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
		44	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.

Sodium Chloride 0.9% 1000 ml AUS	1 Number	5	Sodium Chloride (SANAL) (EP)	9.45 gm
		10	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		15	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		20	SSC Infusion (0434181)	Net content in export + 1% wastage.
		25	SSC Injection (Art. 0434371)	Net content in export + 1% wastage.
		30	SF9-11 195/140 Prim. film (Art.0369631)1 ltr	Net content in export + 1% wastage.
		35	OFR2-11 120/524-500 ml and 1000 ml (0369681)	Net content in export + 1% wastage.
		40	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
		45	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.

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

Case No.	46 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026

Date				
HQ File Number	HQRNORM REVIW00003348AM26			
RA File Number	52AX04000128 AM24			
Licence No and Date	5211005508/21/08/2023			
Norms Committee Decision:				
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-{1- [(2S)-2-Aminopropyl]-1-H- Pyrazole-3-yl}-2- Chlorobenzonitrile)	1 kg.	1	Tert-Butyl((1S)-2-hydroxy-1-methylethyl) carbamate	1.70 kg.
		2	Diisopropyl azodicarboxylate	1.96 kg.
			3	Triphenylphosphine
RA concerned may take further necessary action as per above decision of NC-III.				

Case No.	47 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00005822AM24
RA File Number	03AX04002768 AM24
Licence No and Date	0311027333/22/09/2023
Norms Committee Decision:	
The Committee examined the request of the firm for fixation of ad-hoc norms . After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from	

the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sodium Chloride 0.9% 50 ml (AUS)	1 Number	1	Sodium Chloride (SANAL) (EP)	0.4725 gm.
		6	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		11	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		16	SSC Infusion (0434181)	Net content in export + 1% wastage.
		21	SSC Injection (Art. 0434371)	Net content in export + 1% wastage.
		26	SF9-11 195/95 Prim.film (0369581) 50 and 100 ml	Net content in export + 1% wastage.
		31	OFR2-11 150/524 for 50 and 100 ml (0369701)	Net content in export + 1% wastage.
		36	UFR2-11 150/524-50ml to 1000 (0369661)	Net content in export + 1% wastage.
		41	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.

Sodium Chloride 0.9 % 100 ml (AUS)	1 Number	2	Sodium Chloride (SANAL) (EP)	0.945 gm.
		7	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		12	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		17	SSC Infusion (0434181)	Net content in export + 1% wastage.
		22	SSC Injection (Art. 0434371)	Net content in export + 1% wastage.
		27	SF9-11 195/95 Prim.film (0369581) 50 and 100 ml	Net content in export + 1% wastage.
		32	OFR2-11 150/524 for 50 and 100 ml (0369701)	Net content in export + 1% wastage.
		37	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
		42	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
Sodium Chloride 0.9% 250 ml (AUS)	1 Number	3	Sodium Chloride (SANAL) (EP)	2.3625 gm.
		8	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.

		13	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		18	SSC Infusion (0434181)	Net content in export + 1% wastage.
		23	SSC Injection (Art. 0434371)	Net content in export + 1% wastage.
		28	SF9-11 195/100 Prim. Film (Art.0369591)	Net content in export + 1% wastage.
		33	OFR2-11 150/524 for 50 and 100 ml (0369701)	Net content in export + 1% wastage.
		38	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
		43	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
Sodium Chloride 0.9% 500 ml (AUS)	1 Number	4	Sodium Chloride (SANAL) (EP)	4.725 gm.
		9	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		14	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		19	SSC Infusion (0434181)	Net content in

				export + 1% wastage.
		24	SSC Injection(Art. 0434371)	Net content in export + 1% wastage.
		29	SF9-11 195/135 Prim film Art. 0369621) 500 ml	Net content in export + 1% wastage.
		34	OFR2-11 120/524-500ml and 1000 ml (0369681)	Net content in export + 1% wastage.
		39	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
		44	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
Sodium Chloride 0.9% 1000 ml AUS	1 Number	5	Sodium Chloride (SANAL) (EP)	9.45 gm.
		10	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		15	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		20	SSC Infusion (0434181)	Net content in export + 1% wastage.
		25	SSC Injection (Art. 0434371)	Net content in export + 1%

					wastage.
			30	SF9-11 195/140 Prim. film (Art.0369631)1 ltr	Net content in export + 1% wastage.
			35	OFR2-11 120/524-500 ml and 1000 ml (0369681)	Net content in export + 1% wastage.
			40	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
			45	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
RA concerned may take further necessary action as per above decision of NC.					

Case No.	48 / NC/3/MEET/Apr/202627/1				
Case Status	Case Approved				
Party Name	ACUTAAS CHEMICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026				
HQ File Number	HQRNORM REVIW00004069AM26				
RA File Number	52AX04000234 AM24				
Licence No and Date	5211006397/10/11/2023				
Norms Committee Decision:					
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-					
Export Product		Qty.	Sl. No.	Import Items	Qty.

				allowed.
4-{1- [(2S)-2-Aminopropyl]-1-H- Pyrazole-3-yl}-2- Chlorobenzonitrile)	1 kg.	1	Tert-Butyl((1S)-2-hydroxy-1-methylethyl) carbamate	1.70 kg.
		2	Diisopropyl azodicarboxylate	1.96 kg.
		3	Triphenylphosphine	2.54 kg.
		4	2-chloro-4-(1H-pyrazol-3-yl) benzonitrile	0.963 kg.

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

Case No.	49 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00008210AM24
RA File Number	05AX04003445 AM24
Licence No and Date	0511023507/30/01/2024
Norms Committee Decision: The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the firm was advised to submit the following documents/information:- I. To give balance chemical reaction indicating molecular weight of all the reactants and product with stage wise yield of the reaction. II. To indicate where Alumino Silicate catalyst, Denatured Ethyl alcohol and methanol are used in the chemical reaction, giving their application/use. III. Calculation of the requirement of all the chemicals with justification of low yield, if any. IV. In chemical reaction Ethyl acetate has been shown as one of the reactants whereas the same	

has neither been shown in import nor in indigenous inputs.

Case No.	50 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	YELLOWSTONE FINE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00008613AM24
RA File Number	03AX04005249 AM24
Licence No and Date	0311031269/16/02/2024
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Molecular weight of export product.	

Case No.	51 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00009103AM24
RA File Number	03AX04005671 AM24
Licence No and Date	0311032149/14/03/2024
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms . After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sodium Chloride 0.9% 50 ml (AUS)	1 Number	1	Sodium Chloride (SANAL) (EP)	0.4725 gm.
		6	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		11	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		16	SSC Infusion (0434181)	Net content in export + 1% wastage.
		21	SSC Injection (Art. 0434371)	Net content in export + 1% wastage.
		26	SF9-11 195/95 Prim.film (0369581) 50 and 100 ml	Net content in export + 1% wastage.
		31	OFR2-11 150/524 for 50 and 100 ml (0369701)	Net content in export + 1% wastage.
		36	UFR2-11 150/524-50ml to 1000 (0369661)	Net content in export + 1% wastage.
		41	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
Sodium Chloride 0.9 % 100 ml (AUS)	1 Number	2	Sodium Chloride (SANAL) (EP)	0.945 gm.

		7	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		12	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		17	SSC Infusion (0434181)	Net content in export + 1% wastage.
		22	SSC Injection (Art. 0434371)	Net content in export + 1% wastage.
		27	SF9-11 195/95 Prim.film (0369581) 50 and 100 ml	Net content in export + 1% wastage.
		32	OFR2-11 150/524 for 50 and 100 ml (0369701)	Net content in export + 1% wastage.
		37	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
		42	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
Sodium Chloride 0.9% 250 ml (AUS)	1 Number	3	Sodium Chloride (SANAL) (EP)	2.3625 gm.
		8	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		13	BOP Injection	Net content in

			(Art. 0434481)	export + 1% wastage.
		18	SSC Infusion (0434181)	Net content in export + 1% wastage.
		23	SSC Injection (Art. 0434371)	Net content in export + 1% wastage.
		28	SF9-11 195/100 Prim. Film (Art.0369591)	Net content in export + 1% wastage.
		33	OFR2-11 150/524 for 50 and 100 ml (0369701)	Net content in export + 1% wastage.
		38	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
		43	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
Sodium Chloride 0.9% 500 ml (AUS)	1 Number	4	Sodium Chloride (SANAL) (EP)	4.725 gm.
		9	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		14	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		19	SSC Infusion (0434181)	Net content in export + 1%

				wastage.
		24	SSC Injection(Art. 0434371)	Net content in export + 1% wastage.
		29	SF9-11 195/135 Prim film Art. 0369621) 500 ml	Net content in export + 1% wastage.
		34	OFR2-11 120/524-500ml and 1000 ml (0369681)	Net content in export + 1% wastage.
		39	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
		44	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
Sodium Chloride 0.9% 1000 ml AUS	1 Number	5	Sodium Chloride (SANAL) (EP)	9.45 gm.
		10	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage.
		15	BOP Injection (Art. 0434481)	Net content in export + 1% wastage.
		20	SSC Infusion (0434181)	Net content in export + 1% wastage.
		25	SSC Injection (Art. 0434371)	Net content in export + 1% wastage.

		30	SF9-11 195/140 Prim. film (Art.0369631)1 ltr	Net content in export + 1% wastage.
		35	OFR2-11 120/524-500 ml and 1000 ml (0369681)	Net content in export + 1% wastage.
		40	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage.
		45	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.

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

Case No.	52 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM REVIW00005461AM26
RA File Number	52AX04000061 AM25
Licence No and Date	5211008490/13/06/2024
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,2,4 - Triazolo (4,3-a) Pyridin - 3 (2H) - one - 98% MIN.	1 kg.	1	Hydrazine Hydrate 64% (RM for mfg of Semicarbazide HCL for further mfg of TPO)	2.14 kg.
		2	2-Chloro Pyridine	1.33 kg.
		3	Ethylene Glycol Monoethyl Ether/2-Ethoxy Ethanol	1.35 kg.

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

Case No.	53 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	PI INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00003572AM25
RA File Number	13AX04000225 AM25
Licence No and Date	1311003391/09/10/2024

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dicloromezotiaz Technical (ZI2901)(Chemical Name : 1-	1 kg.	1	2-Chloro-5-Chloromethylthiazole	0.57 kg.

[(2-chlorothiazol-5-yl)methyl]-3-(3,5-dichlorophenyl)-9-methyl-2,4-dioxo-3,4-dihydro-2H-1?5-pyrido[1,2-a]pyrimidin-1-ylum-3-ide)		2	Potassium Carbonate	1.42 kg.
		3	3,5-Dichlorobenzoyl Chloride	1.02 kg.
		4	Dimethyl Carbonate	0.89 kg.
		5	Acetonitrile	1.03 kg.

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

Case No.	54 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00003633AM25
RA File Number	03AX04003448 AM25
Licence No and Date	0311037925/15/10/2024

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
5-[1-Methyl (sulfanyl) ethyl]-2-(trifluoromethyl) pyridine (PSI)	1 kg.	1	Trifluoroacetyl	0.9 kg.
		2	Ethyl Vinyl Ether (EVE)	0.50 kg.

		3	21% Sodium Thiomethoxide	2.30 kg.
		4	Pyrrolidine	0.45 kg.
RA concerned may take further necessary action as per above decision of NC-III.				

Case No.	55 / NC/3/MEET/Apr/202627/1										
Case Status	Case Approved										
Party Name	PARADISE HEALTHCARE										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026										
HQ File Number	HQRNORM APPLY 00003965AM25										
RA File Number	34AX04000658 AM25										
Licence No and Date	3411005628/30/10/2024										
Norms Committee Decision:											
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>6-chloro-4-hydroxy-2-methyl-2H-thieno[2,3-e][1,2]thiazine-3-carboxylate 1,1-dioxide</td><td>1 kg.</td><td>1</td><td>Methyl 3-Amino-2-thiophenecarboxylate 97% Min</td><td>3.15 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	6-chloro-4-hydroxy-2-methyl-2H-thieno[2,3-e][1,2]thiazine-3-carboxylate 1,1-dioxide	1 kg.	1	Methyl 3-Amino-2-thiophenecarboxylate 97% Min	3.15 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
6-chloro-4-hydroxy-2-methyl-2H-thieno[2,3-e][1,2]thiazine-3-carboxylate 1,1-dioxide	1 kg.	1	Methyl 3-Amino-2-thiophenecarboxylate 97% Min	3.15 kg.							
RA concerned may take further necessary action as per above decision of NC-III.											

Case No.	56 / NC/3/MEET/Apr/202627/1
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Case Status	Case Approved													
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026													
HQ File Number	HQRNORM APPLY 00004814AM25													
RA File Number	03AX04004624 AM25													
Licence No and Date	0311039663/16/12/2024													
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:- <table border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> <tr> <td rowspan="2">Povidone Iodine USP</td><td rowspan="2">1 kg.</td><td>1</td><td>Iodine</td><td>0.120 kg.</td></tr> <tr> <td>2</td><td>Polyvinylpyrrolidone</td><td>0.800 kg.</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC-III.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Povidone Iodine USP	1 kg.	1	Iodine	0.120 kg.	2	Polyvinylpyrrolidone	0.800 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Povidone Iodine USP	1 kg.	1	Iodine	0.120 kg.										
		2	Polyvinylpyrrolidone	0.800 kg.										

Case No.	57 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00004895AM25
RA File Number	05AX04003211 AM25
Licence No and Date	0511029723/19/12/2024
Norms Committee Decision: The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the firm was advised submit the following information/documents:-	

- I. To give balance chemical reaction indicating molecular weight of all the reactants and product with stage wise yield of their action/
- II. Process flow charts indicating where Alumino Silicate Catalyst, Denatured Ethyl Alcohol and Methanol are used in the chemical reaction giving their application/use.
- III. Calculation of the requirement of all the chemicals with justification of low yield.

Case No.	58 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	PARADISE HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00005333AM25
RA File Number	34AX04000854 AM25
Licence No and Date	3411005897/01/01/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
6-chloro-4hydroxy-2-methyl-3-Methoxycarbonyl-2h-thieno[2,3-e][1,2] thiazine-11Dioxide	1 kg.	1	Methyl 3-Amino-2 thiophenecarboxylate 97% Min	3.15 kg.

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

Case No.	59 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	PARAGON FINE AND SPECIALITY CHEMICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00000004AM26

RA File Number	08AX04002207 AM25
Licence No and Date	0811014582/01/04/2025
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Percentage Yield of reaction. 2. Commercial value of by-product obtained. 3. Justification for import of water.	

Case No.	60 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	PARAGON FINE AND SPECIALITY CHEMICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00000005AM26
RA File Number	08AX04002208 AM25
Licence No and Date	0811014583/01/04/2025
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Justification of low yield of 72%. 2. Commercial value of by-product acetic acid obtained. 3. Justification of import of water	

Case No.	61 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	PARAGON FINE AND SPECIALITY CHEMICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026

HQ File Number	HQRNORM APPLY 00000076AM26
RA File Number	08AX04002246 AM25
Licence No and Date	0811014626/03/04/2025
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Bill of entry to indicate the purity of K-Acid as 70% (as indicated in the process). 2. Justification for import of Ice.	

Case No.	62 / NC/3/MEET/Apr/202627/1																
Case Status	Case Approved																
Party Name	BENZO CHEM INDUSTRIES PVT LTD																
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026																
HQ File Number	HQRNORM APPLY 00000087AM26																
RA File Number	03AX04000001 AM26																
Licence No and Date	0311042847/04/04/2025																
Norms Committee Decision:																	
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-																	
<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">3 Iso Chromanone (3 I C)</td><td rowspan="2">1 kg.</td><td>1</td><td>Ortho Methyl Phenyl Acetic Acid</td><td>1.40 kg.</td></tr><tr><td>2</td><td>Mono Chloro Benzene</td><td>0.30 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	3 Iso Chromanone (3 I C)	1 kg.	1	Ortho Methyl Phenyl Acetic Acid	1.40 kg.	2	Mono Chloro Benzene	0.30 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
3 Iso Chromanone (3 I C)	1 kg.	1	Ortho Methyl Phenyl Acetic Acid	1.40 kg.													
		2	Mono Chloro Benzene	0.30 kg.													

		3	Liquid Chlorine	0.65 kg.
		4	2,2-Azobis iso butyro nitrile (AIBN / Cat-X)	0.02 kg.
		5	Sodium Hydroxide (Caustic Soda Lye)	0.50 kg.
		6	Sodium Bi Carbonate	0.20 kg.
		7	Hydro Chloric Acid (HCL 30%)	0.50 kg.
		8	Methanol	0.30 kg.

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

Case No.	63 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	LA CHANDRA PHARMALAB PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00000242AM26
RA File Number	08AX04000065 AM26
Licence No and Date	0811014717/15/04/2025
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Mifepristone (N.A.)	1 kg.	1	N 1 Mifepristone (NA)	1.15 kg.

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

Case No.	64 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	SRS FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001216AM26
RA File Number	03AX04000936 AM26
Licence No and Date	0311044395/02/06/2025
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix-4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Please furnish export quantity in Numbers or Sachets in line with Drug Manufacturing Licence. 2. Weight of each Sachet. 3. Copy of Master-Batch Formula for export item.	

Case No.	65 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001233AM26

RA File Number	03AX04000913 AM26
Licence No and Date	0311044428/02/06/2025
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents from the firm: Copy of Master-Batch Formula for each export item.	

Case No.	66 / NC/3/MEET/Apr/202627/1															
Case Status	Case Approved															
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026															
HQ File Number	HQRNORM APPLY 00001256AM26															
RA File Number	08AX04000384 AM26															
Licence No and Date	0811015193/03/06/2025															
Norms Committee Decision:																
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-																
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Zinc Sulfate Injection USP, 1 mg / ml (10 ml)</td><td>1 Number</td><td>1</td><td>Zinc sulphate heptahydrate</td><td>48.378 mg.</td></tr><tr><td>Zinc Sulfate Injection USP, 5 mg / ml (5 ml)</td><td>1 Number</td><td>2</td><td>Zinc sulphate heptahydrate</td><td>120.944 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Zinc Sulfate Injection USP, 1 mg / ml (10 ml)	1 Number	1	Zinc sulphate heptahydrate	48.378 mg.	Zinc Sulfate Injection USP, 5 mg / ml (5 ml)	1 Number	2	Zinc sulphate heptahydrate	120.944 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Zinc Sulfate Injection USP, 1 mg / ml (10 ml)	1 Number	1	Zinc sulphate heptahydrate	48.378 mg.												
Zinc Sulfate Injection USP, 5 mg / ml (5 ml)	1 Number	2	Zinc sulphate heptahydrate	120.944 mg.												

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

Case No.	67 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001261AM26
RA File Number	07AX04000383 AM26
Licence No and Date	0711014615/03/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Phloroglucinol 160 mg OD Tablets	1 Number	1	Phloroglucinol Dihydrate BP/EP/IP/USP	163.2 mg.

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

Case No.	68 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001273AM26
RA File Number	03AX04001066 AM26

Licence No and Date	0311044429/04/06/2025			
Norms Committee Decision:				
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MOXILEB -CV -375 TABLET USP. (AMOXICILLIN & CLAVULANATE POTASSIUM TABLETS USP 375 MG) (EACH TABLET CONTAINING AMOXICILLIN TRIHYDRATE EQUIVALENT TO 250 MG OF AMOXICILLIN) NET CONTENT OF IMPORT / EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE USP (COMPACTED) EXTRADRY - 49.709 KG (EXCL 2% WASTAGE)	1 Number	1	Amoxicillin Trihydrate USP Compacted	292.639 mg.
MOXILEB -CV -625 TABLET USP. (AMOXICILLIN & CLAVULANATE POTASSIUM TABLETS USP 625 MG). (EACH TABLET CONTAINING AMOXICILLIN TRIHYDRATE EQUIAVLENT TO 500 MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE USP COMPACTED) EXTRA DRY - 128.117KG (EXCL 2% WASTAGE)	1 Number	2	Amoxicillin Trihydrate USP Compacted	585.28 mg.
MOXILEB -CV -1000TABLET USP.	1 Number	3	Amoxicillin Trihydrate	892.511 mg.

(AMOXICILLIN & CLAVULANATE POTASSIUM TABLETS USP 1000 MG) (EACH TABLET CONTAINING AMOXICILLIN TRIHYDRATE EQUIVALENT TO 875 MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE USP (COMPACTED) EXTRA DRY - 238.359 KG (EXCL 2% WASTAGE)			USP Compacted	
MOXILEB -CV -156.25 DRY SYRUP USP. (AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORAL SUSPENSION USP 156.25MG/5ML) ((EACH 5ML CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO 125MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1 AMOXICILLIN TRIHYDRATE USP (COMPACTED) EXTRA DRY -44.083KG (EXCL 2% WASTAGE)) 100 ml Bottle.	1 Number	4	Amoxicillin Trihydrate USP Compacted	2625 mg.
MOXILEB -CV -228.5 DRY SYRUP USP. (AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORAL SUSPENSION USP 228.5 MG/5ML) ((EACH 5ML CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO 200 MG OF AMOXICILLIN) . NET CONTENT OF IMPORT /EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE USP (COMPACTED) EXTRA DRY - 87.202KG (EACL 2% WASTAGE) 100 ml. Bottle.	1 Number	5	Amoxicillin Trihydrate USP Compacted	4200.0 mg.
MOXILEB -CV -457 DRY SYRUP USP. (AMOXICILLIN AND	1 Number	6	Amoxicillin Trihydrate USP Compacted	6384.0 mg.

CLAVULANATE POTASSIUM FOR ORAL SUSPENSION USP 457MG/5ML)((EACH 5ML CONTIANS AMOXICILLIN TRIHYDRATE EQUIVALENT TO 400MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE USP (COMPACTED) EXTRA DRY - 187.825 KG (EXCL 2% WASTAGE) 70 ml. Bottle.				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	69 / NC/3/MEET/Apr/202627/1			
Case Status	Case Approved			
Party Name	SAGAR LIFE SCIENCES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026			
HQ File Number	HQRNORM APPLY 00001284AM26			
RA File Number	34AX04000209 AM26			
Licence No and Date	3411006552/04/06/2025			
Norms Committee Decision:				
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-				
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		2	Trimethylsilyl chloride	3619.528 kg.
RA concerned may take further necessary action as per above decision of NC-III.				

Case No.	70 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001294AM26
RA File Number	05AX04000712 AM26
Licence No and Date	0511033130/05/06/2025

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. 0511024949 dated 10/04/2024 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.
Meropenem Sodium Sterile (Meropenem for Injection)	1 kg.	1	Meropenem Trihydrate (Non Sterile)	0.8968 kg.

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

Case No.	71 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	INTIGREAT CONSULTING SERVICES LLP

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001313AM26
RA File Number	03AX04001090 AM26
Licence No and Date	0311044509/05/06/2025
Norms Committee Decision: In this application, it is observed that the import item and export product are essentially the same/similar in description, character and use, with no substantial manufacturing process resulting in transformation into a distinct product having a different name, character or use. Para 4.03 of FTP provides for duty-free import of inputs that are physically incorporated in the export product after undergoing a process of manufacture. The scheme contemplates admissibility of inputs required for manufacture of resultant export products and not for mere trading, repacking, relabeling, or negligible processing where the imported and exported goods remain essentially identical. Since the proposed export product does not emerge as a distinct manufactured product from the imported material, the request for fixation of norms is not found admissible under Para 4.03 of FTP. Accordingly, the application for the fixation of ad hoc/input-output norms is rejected. RA is requested to initiate recovery of duty and interest for imported items as per applicable provisions of FTP and HBP read with the FTDR Act.	

Case No.	72 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001326AM26
RA File Number	09AX04000229 AM26
Licence No and Date	0911009779/06/06/2025
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	73 / NC/3/MEET/Apr/202627/1
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Case Status	Case Approved
Party Name	INDO AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001349AM26
RA File Number	03AX04001084 AM26
Licence No and Date	0311044547/06/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Benzoguanamine or IAL BGA	1 kg.	1	Dicyandiamide	0.499 kg.
		2	Enzonitrile	0.612 kg.
		3	N-Butanol	0.750 kg.

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

Case No.	74 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	APITORIA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001359AM26
RA File Number	09AX04000237 AM26
Licence No and Date	0911009784/06/06/2025

Norms Committee Decision:

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

Case No.	75 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	STERLING AUXILIARIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001398AM26
RA File Number	03AX04001199 AM26
Licence No and Date	0311044637/10/06/2025
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: Percentage purity of export product.	

Case No.	76 / NC/3/MEET/Apr/202627/1			
Case Status	Case Approved			
Party Name	SANOFI CONSUMER HEALTHCARE INDIA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026			
HQ File Number	HQRNORM APPLY 00001399AM26			
RA File Number	03AX04001131 AM26			
Licence No and Date	0311044640/10/06/2025			
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/202526/6 dated 18/12/2025 against advance authorization No. 0311042739 dated 01/04/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Festal (Tablets) Enterosolube 10 x 10s ((Total Net Weight of Pancreatin 18691.60 kgs Strength of Pancreatin 192 mg/Tablet))	1 Number Tablet	1	Pancreatin	195.84 mg
RA concerned may take further necessary action as per above decision of NC				

Case No.	77 / NC/3/MEET/Apr/202627/1													
Case Status	Case Approved													
Party Name	SANOFI CONSUMER HEALTHCARE INDIA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026													
HQ File Number	HQRNORM APPLY 00001400AM26													
RA File Number	03AX04001116 AM26													
Licence No and Date	0311044641/10/06/2025													
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/202526/6 dated 18/12/2025 against advance authorization No. 0311042739 dated 01/04/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Festal (Tablets) Enterosolube 10 x 10s ((Total Net Weight of Pancreatin 18691.60 kgs Strength of Pancreatin 192 mg/Tablet))</td><td>1 Number Tablet</td><td>1</td><td>Pancreatin</td><td>195.84 mg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Festal (Tablets) Enterosolube 10 x 10s ((Total Net Weight of Pancreatin 18691.60 kgs Strength of Pancreatin 192 mg/Tablet))	1 Number Tablet	1	Pancreatin	195.84 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Festal (Tablets) Enterosolube 10 x 10s ((Total Net Weight of Pancreatin 18691.60 kgs Strength of Pancreatin 192 mg/Tablet))	1 Number Tablet	1	Pancreatin	195.84 mg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	78 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved

Party Name	SYDLER REMEDIES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026													
HQ File Number	HQRNORM APPLY 00001401AM26													
RA File Number	03AX04001215 AM26													
Licence No and Date	0311044648/10/06/2025													
Norms Committee Decision:														
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Ursodeoxycholic Acid Granules namely UDCA 200 mg. DC Granules (Net content 0.6765 of export qty.)</td><td>1 kg.</td><td>1</td><td>Ursodeoxycholic Acid Powder</td><td>0.69 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ursodeoxycholic Acid Granules namely UDCA 200 mg. DC Granules (Net content 0.6765 of export qty.)	1 kg.	1	Ursodeoxycholic Acid Powder	0.69 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Ursodeoxycholic Acid Granules namely UDCA 200 mg. DC Granules (Net content 0.6765 of export qty.)	1 kg.	1	Ursodeoxycholic Acid Powder	0.69 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	79 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001423AM26
RA File Number	05AX04000851 AM26
Licence No and Date	0511033239/10/06/2025
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/Feb/202526/13 dated 20/02/2026 against advance authorization No. 0511032819 dated 23/05/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm,	

whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ceftriaxone Sodium Sterile	1 kg.	1	Ceftriaxone Sodium (Non Sterile)	1.04 kg.

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

Case No.	80 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001424AM26
RA File Number	52AX04000071 AM26
Licence No and Date	5211014068/10/06/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	81 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001448AM26
RA File Number	05AX04000950 AM26
Licence No and Date	0511033264/11/06/2025
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/Oct/202526/9 dated 14/10/2025 against advance authorization No. 3011006688 dated 19/03/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sugammadex Injection, 100 mg/ml, 2 ml.	1 Number	1	Sugammadex Sodium	239.326 mg.

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

Case No.	82 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001449AM26
RA File Number	03AX04001143 AM26
Licence No and Date	0311044707/11/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2,4-Dichloro Benzaldehyde (2,4-DCB)	1 kg.	1	2, 4 - Dichloro toluene (2.4-DCT)	1.083 kg.

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

Case No.	83 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ASTA BIOCHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001458AM26
RA File Number	07AX04000427 AM26
Licence No and Date	0711014690/11/06/2025

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/Feb/202526/13 dated 20/02/2026 against advance authorization No. 0711014435 dated 15/05/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.
Calcium Thioglycolate (Imported Item Output is 99,500 kg. and Domestic Content is 17,219 kg. and Total Export Item Weight 116,719 kg.)	1 Kg.	1	Thioglycolic Acid	0.927 Kg.

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

Case No.	84 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026

HQ File Number	HQRNORM APPLY 00001477AM26
RA File Number	03AX04001076 AM26
Licence No and Date	0311044748/12/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Mometasone Furoate & Azelastine HCL Nasal Spray (50 mcg + 140 mcg) 150 MD ((Glenspray Active/Modexa AZ/ Momat A Nasal Spray/Momat Rino Advance/Momate - AZ/Nasalsona Plus) (Net Wt. of Import Sr. No. 1 is 7585.09 Grams and Import Sr. No. 2 is 21238.25 Grams))	1011345 Numbers	1	Mometasone Furoate BP	3825 gm.
		2	Azelastine Hydrochloride BP	21663.3 gm.
Mometasone Furoate & Azelastine HCL Nasal Spray (50 mcg + 140 mcg) 75 MD ((Glenspray Active/Modexa AZ/ Momat A Nasal Spray/Momat Rino Advance/Momate – AZ / Nasalsona Plus) (Net Wt. of Import Sr. No. 1 is 1879.54 Grams and Import Sr. No.2 is 5262.71 Grams))	501210 Numbers	3	Mometasone Furoate BP	1917.13 gm.
		4	Azelastine Hydrochloride BP	5367.96 gm.

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

Case No.	85 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	SVR DRUGS AND INTERMEDIATES
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001480AM26
RA File Number	07AX04000404 AM26
Licence No and Date	0711014713/12/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cis Tosylate	1 kg.	1	Para Toluene sulphonyl chloride	0.395 kg.
		2	Imidazole	0.141 kg.
		3	Benzoyal Chloride	0.582 kg.
		4	2,4 Dichloro Acetophenone	0.783 kg.
		5	Glycerine	0.381 kg.

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

Case No.	86 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026																		
HQ File Number	HQRNORM APPLY 00001483AM26																		
RA File Number	09AX04000210 AM26																		
Licence No and Date	0911009815/12/06/2025																		
Norms Committee Decision:																			
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-																			
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Sacubitril Valsartan Sodium Tablets 50 mg (Consists of 42 Kgs of Sacubitril Valsartan Sodium) Pack Size : 28s)</td> <td>1 Number Tablet</td> <td>1</td> <td>Sacubitril Valsartan Sodium</td> <td>51.0 mg.</td> </tr> <tr> <td>Sacubitril Valsartan Sodium Tablets 100 mg (Consists of 84 Kgs of Sacubitril Valsartan Sodium) Pack Size : 28s</td> <td>1 Number Tablet</td> <td>2</td> <td>Sacubitril Valsartan Sodium</td> <td>102.0 mg</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sacubitril Valsartan Sodium Tablets 50 mg (Consists of 42 Kgs of Sacubitril Valsartan Sodium) Pack Size : 28s)	1 Number Tablet	1	Sacubitril Valsartan Sodium	51.0 mg.	Sacubitril Valsartan Sodium Tablets 100 mg (Consists of 84 Kgs of Sacubitril Valsartan Sodium) Pack Size : 28s	1 Number Tablet	2	Sacubitril Valsartan Sodium	102.0 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Sacubitril Valsartan Sodium Tablets 50 mg (Consists of 42 Kgs of Sacubitril Valsartan Sodium) Pack Size : 28s)	1 Number Tablet	1	Sacubitril Valsartan Sodium	51.0 mg.															
Sacubitril Valsartan Sodium Tablets 100 mg (Consists of 84 Kgs of Sacubitril Valsartan Sodium) Pack Size : 28s	1 Number Tablet	2	Sacubitril Valsartan Sodium	102.0 mg															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	87 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001490AM26
RA File Number	52AX04000074 AM26
Licence No and Date	5211014358/13/06/2025
Norms Committee Decision:	

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Triamcinolone Acetonide IP/EP/BP/USP	1 kg.	1	3,20-Dioxopregna-1,4,9 (11),16 - Tetraen - 21- Ylacetate (3 TR)	1.05 kg.

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

Case No.	88 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	BRAWN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001508AM26
RA File Number	05AX04000958 AM26
Licence No and Date	0511033337/16/06/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	89 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001515AM26
RA File Number	52AX04000087 AM26

Licence No and Date	5211014419/16/06/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	90 / NC/3/MEET/Apr/202627/1													
Case Status	Case Approved													
Party Name	MACSON PRODUCTS													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026													
HQ File Number	HQRNORM APPLY 00001516AM26													
RA File Number	52AX04000079 AM26													
Licence No and Date	5211014420/16/06/2025													
Norms Committee Decision:														
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Schaffers Acid (Highly Purified)</td><td>1 kg.</td><td>1</td><td>Beta Naphthol</td><td>0.80 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Schaffers Acid (Highly Purified)	1 kg.	1	Beta Naphthol	0.80 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Schaffers Acid (Highly Purified)	1 kg.	1	Beta Naphthol	0.80 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	91 / NC/3/MEET/Apr/202627/1			
Case Status	Case Approved			
Party Name	MEDREICH LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026			
HQ File Number	HQRNORM APPLY 00001517AM26			
RA File Number	07AX04000443 AM26			

Licence No and Date	0711014735/16/06/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Sep/202526/8 dated 17/09/2025 against advance authorization No. 0711013518 dated 30/01/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Clindamycin Hydrochloride 300 mg Capsules [1628.900 kg.] [Each Capsule contains Clindamycin Hydrochloride 325.78 mg equivalent to Clindamycin 300 mg])	1 Number	1	Clindamycin Hydrochloride Ph.Eur	332.29 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	92 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ENVEE DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001518AM26
RA File Number	34AX04000156 AM26
Licence No and Date	3411006600/16/06/2025
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Sep/202526/8 dated 17/09/2025 against advance authorization No. 0711013518 dated 30/01/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Prednisolone Sodium Metasulfobenzoate	1 kg.	1	Prednisolone (EP/BP/USP)	1.00 kg.

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

Case No.	93 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	APITORIA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001520AM26
RA File Number	09AX04000282 AM26
Licence No and Date	0911009831/16/06/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	94 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	SHREAS INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001534AM26
RA File Number	09AX04000256 AM26
Licence No and Date	0911009849/17/06/2025
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jan/202526/12 dated	

15/01/2026 against advance authorization No. 0911009590 dated 08/05/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Methylene Chloride (Methylene Di-Chloride/ Di- Chloromethane)	1 kg.	1	Methanol	0.418 kg.

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

Case No.	95 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	STYRAX PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001535AM26
RA File Number	09AX04000246 AM26
Licence No and Date	0911009850/17/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
5-(4-Amino-2-Oxo-Pyrimidinyl)-Oxathiolane-2-Carboxylic Acid-	1 kg.	1	L-Menthyl Glyoxylate Hydrate (L-MGH)	0.81 kg

Isopropylmethyl-Cyclohexyl Ester or CHE)	2	2,5-Dihydroxy-1,4-Diathine	0.312 kg
	3	Di Methyl Formamide (DMF)	0.26 kg
	4	Cytosine	0.395 kg
	5	Hexa Methyl Disilazane (HMDS)	0.286 kg
	6	Methylene Di Chloride (MDC)	2.63 kg
	7	Tri Ethyl Amine (TEA)	0.034 kg
	8	Triphosgene	0.40 kg
RA concerned may take further necessary action as per above decision of NC-III.			

Case No.	96 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	SPAR PHARMA LLP
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001536AM26
RA File Number	09AX04000248 AM26
Licence No and Date	0911009851/17/06/2025
Norms Committee Decision: The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Oct/202526/5 dated 14/01/2025 against Advance Authorisation No. 0911009149 dated 06/03/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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.	97 / NC/3/MEET/Apr/202627/1			
Case Status	Case Approved			
Party Name	DEEPAK NOVOCHEM SPECIALITIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026			
HQ File Number	HQRNORM APPLY 00001537AM26			
RA File Number	31AX04000107 AM26			
Licence No and Date	3111004980/17/06/2025			
Norms Committee Decision:				
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Oct/202526/9 dated 14/01/2025 against Advance Authorisation No. 3111004443 dated 17/12/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

2,6 Xylenol	1 kg.	1	Phenol	0.963 kg.
		2	Methanol	0.750 kg.
		3	Catalyst (Katalco)	0.004 kg.

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

Case No.	98 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM SPECIALITIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001538AM26
RA File Number	31AX04000106 AM26
Licence No and Date	3111004981/17/06/2025

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Oct/202526/9 dated 14/01/2025 against Advance Authorisation No. 3111004443 dated 17/12/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

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

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

Case No.	99 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001542AM26
RA File Number	34AX04000188 AM26
Licence No and Date	3411006619/17/06/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Apr/202526/2 dated 08/05/2025 against advance authorization No. 3411005503 dated 08/10/2024, 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.
Duloxetine Caps. 20 mg (Net content of active ingredients 180.000 kgs)	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	22.88 mg.
		2	Sugar Spheres (30-35 PHARM-A-SPHERES)	20.33 mg.
		3	Sucrose (CompressucPS)	50.67 mg.
Duloxetine Caps. 30 mg (Net content of active ingredients 750.00 kgs)	1 Number Capsule	4	Duloxetine Hydrochloride Ph,Eur.	34.36 mg.
		5	Sugar Spheres (30-35 PHARM-A-SPHERES)	30.50 mg.
		6	Sucrose (CompressucPS)	23.50 mg

Duloxetine Caps. 40 mg (Net content of active ingredients 360.000 kgs)	1 Number Capsule	7	Duloxetine Hydrochloride Ph,Eur.	45.76 mg
		8	Sugar Spheres (30-35 PHARM-A-SPHERES)	40.67 mg.
		9	Sucrose (CompressucPS)	31.34 mg.
Duloxetine Caps. 60 mg (Net content of active ingredients 1500.00 kgs)	1 Number Capsule	10	Duloxetine Hydrochloride Ph,Eur.	68.71 mg.
		11	Sugar Spheres (30-35 PHARM-A-SPHERES)	61.00 mg.
		12	Sucrose (CompressucPS)	47.00 mg.

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

Case No.	100 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001552AM26
RA File Number	31AX04000108 AM26
Licence No and Date	3111004982/18/06/2025
Norms Committee Decision:	
The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. The chemical name of the export item DNOVO BP 838.	

2. Difference in DNOVO BP 838 and DNOVO BP 388.

Case No.	101 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001569AM26
RA File Number	52AX04000085 AM26
Licence No and Date	5211014477/19/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-{1- [(2S)-2-Aminopropyl]-1-H- Pyrazole-3-yl}-2- Chlorobenzonitrile)	1 kg.	1	Tert-Butyl((1S)-2-hydroxy-1-methylethyl) carbamate	1.70 kg.
		2	Diisopropyl azodicarboxylate	1.96 kg.
		3	Triphenylphosphine	2.54 kg.

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

Case No.	102 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026													
HQ File Number	HQRNORM APPLY 00001570AM26													
RA File Number	03AX04001413 AM26													
Licence No and Date	0311044919/19/06/2025													
Norms Committee Decision:														
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Dec/202526/11 dated 18/12/2025 against Advance Authorisation No. 0311042932 dated 08/04/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Vibegron (Obgemsa) Tablets 75 mg.</td><td>1 Number</td><td>1</td><td>Vibegron</td><td>76.50 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Vibegron (Obgemsa) Tablets 75 mg.	1 Number	1	Vibegron	76.50 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Vibegron (Obgemsa) Tablets 75 mg.	1 Number	1	Vibegron	76.50 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	103 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	LEE PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001573AM26
RA File Number	09AX04000287 AM26
Licence No and Date	0911009874/19/06/2025
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents:	

1. Stepwise complete and balanced chemical reactions from starting stage with molecular weight. and percentage yield on molar basis.
2. Material balance for each step.
3. Requirement and recovery of solvent of each step.

Case No.	104 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM SPECIALITIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001580AM26
RA File Number	31AX04000110 AM26
Licence No and Date	3111004985/19/06/2025

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Oct/202526/9 dated 14/01/2025 against Advance Authorisation No. 3111004443 dated 17/12/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

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

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

Case No.	105 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred

Party Name	ROSSARI BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001589AM26
RA File Number	03AX04001422 AM26
Licence No and Date	0311044962/20/06/2025
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Complete chemical name of both import items with Certificate of Analysis (CoA). 2. Molecular weight of import and export.	

Case No.	106 / NC/3/MEET/Apr/202627/1	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026	
HQ File Number	HQRNORM APPLY 00001593AM26	
RA File Number	03AX04001373 AM26	
Licence No and Date	0311044978/20/06/2025	
Norms Committee Decision:		
The Committee examined the request of the firm for fixation of ad-hoc norms to facilitate the issuance of Advance Authorization by the concerned Regional Authority. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below.:-		
Sl. No.	Export Product	Quantity
1	Medical Cream,Ointment & Gel (ESTRADIOL GEL 0.06% 50 Gm Pump Wt:1 Number 2750 Kgs (Net Cont: ESTRADIOL 1.65 Kgs, ETHANOL 1147.58 Kgs, CARBOPOL 28.6 Kgs, TROLAMINE 27.50 Kgs, WHITE CAP, WHITE	

	BOTTLE, WHITE PUMP 55000 Nos EACH))	
2	Medical Cream,Ointment & Gel (ESTRADIOL GEL 0.1% , 1.25 Gm Sachet Wt: 750 Kgs (Net Cont: ESTRADIOL 0.75 Kgs, ETHANOL 412.50 Kgs, CARBOPOL 9.75 Kgs, TROLAMINE 2.10 Kgs, PROPYLENE 90 Kgs))	1 Number
3	Medical Cream, Ointment & Gel (ESTRADIOL GEL 0.1% , 0.25 Gm Sachet Wt: 150 Kgs (Net Cont: ESTRADIOL 0.15 Kgs, ETHANOL 82.50 Kgs, CARBOPOL 1.95 Kgs, TROLAMINE 0.42 Kgs, PROPYLENE 18 Kgs))	1 Number
4	Medical Cream, Ointment & Gel (ESTRADIOL GEL 0.1% , 1 Gm Sachet Wt: 600 Kgs (Net Cont: ESTRADIOL 0.6 Kgs, ETHANOL 330.00 Kgs, CARBOPOL 7.8 Kgs, TROLAMINE 1.68 Kgs, PROPYLENE 72 Kgs))	1 Number
5	Medical Cream, Ointment & Gel (ESTRADIOL GEL 0.1% , 0.75 Gm Sachet Wt: 450 Kgs (Net Cont: ESTRADIOL 0.45 Kgs, ETHANOL 247.50 Kgs, CARBOPOL 5.85 Kgs, TROLAMINE 1.26 Kgs, PROPYLENE 54 Kgs))	1 Number
6	Medical Cream,Ointment & Gel (ESTRADIOL GEL 0.1% , 0.50 Gm Sachet Wt: 300 Kgs (Net Cont: ESTRADIOL 0.30 Kgs, ETHANOL 165 Kgs, CARBOPOL 3.90 Kgs, TROLAMINE 0.84 Kgs, PROPYLENE 36 Kgs))	1 Number

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

Note:

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

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

Case No.	107 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001605AM26
RA File Number	07AX04000327 AM26
Licence No and Date	0711014809/20/06/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	108 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001621AM26
RA File Number	03AX04001361 AM26
Licence No and Date	0311045012/23/06/2025
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents from the firm: 1. Past production / consumption data certified by Chartered Accountant alongwith Drug Manufacturing Licence (DML).	

Case No.	109 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	CIRON DRUGS AND PHARMACEUTICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001630AM26
RA File Number	03AX04001469 AM26
Licence No and Date	0311045023/23/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tobramycin & Dexamethasone Ophthalmic Solution 3mg/ml - 5 ml (Each ml contains Tobramycin USP 3 mg) (65,000 Nos) (Protaba Drops (Tobramycin and Dexamethasone Ophthalmic Suspension USP) - 5 ml. Each ml contains : Tobramycin USP(3 mg) Dexamethasone USP (1 mg) Benzalkonium Chloride NF (0.2 mg) (65,000 Nos) Net Content: 1) Tobramycin USP:0.975 KGS)	65000 Numbers	1	Tobramycin USP	1.024 kg.

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

Case No.	110 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001647AM26
RA File Number	07AX04000518 AM26

Licence No and Date	0711014819/24/06/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	111 / NC/3/MEET/Apr/202627/1													
Case Status	Case Approved													
Party Name	GLOBAL CALCIUM PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026													
HQ File Number	HQRNORM APPLY 00001648AM26													
RA File Number	07AX04000517 AM26													
Licence No and Date	0711014820/24/06/2025													
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/202526/5 dated 30/06/2025 against advance authorization No. 0211007647 dated 22/11/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<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.	112 / NC/3/MEET/Apr/202627/1			
Case Status	Case Approved			
Party Name	TIDE INDUSTRIES			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026			
HQ File Number	HQRNORM APPLY 00001659AM26			

RA File Number	34AX04000259 AM26																
Licence No and Date	3411006647/24/06/2025																
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:- <table border="1" data-bbox="197 653 1428 1063"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Gamma Undecalactone (Aldehyde C14)</td> <td rowspan="2">1 kg.</td> <td>1</td> <td>Acrylic Acid</td> <td>0.56 kg.</td> </tr> <tr> <td>2</td> <td>Alcohol C 8 (N-Octanol)</td> <td>1.0 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.	Gamma Undecalactone (Aldehyde C14)	1 kg.	1	Acrylic Acid	0.56 kg.	2	Alcohol C 8 (N-Octanol)	1.0 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Gamma Undecalactone (Aldehyde C14)	1 kg.	1	Acrylic Acid	0.56 kg.													
		2	Alcohol C 8 (N-Octanol)	1.0 kg.													

Case No.	113 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001668AM26
RA File Number	34AX04000264 AM26
Licence No and Date	3411006650/24/06/2025
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Apr/202526/2 dated 08/05/2025 against advance authorization No. 3411005503 dated 08/10/2024, 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.
Duloxetine Caps. 20 mg (Net content of active ingredients 180.000 kgs)	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	22.88 mg.
		2	Sugar Spheres (30-35 PHARM-A-SPHERES)	20.33 mg.
		3	Sucrose (Compressuc PS)	50.67 mg.
Duloxetine Caps. 30 mg (Net content of active ingredients 750.00 kgs)	1 Number Capsule	4	Duloxetine Hydrochloride Ph,Eur.	34.36 mg.
		5	Sugar Spheres (30-35 PHARM-A-SPHERES)	30.50 mg.
		6	Sucrose (Compressuc PS)	23.50 mg
Duloxetine Caps. 40 mg (Net content of active ingredients 360.000 kgs)	1 Number Capsule	7	Duloxetine Hydrochloride Ph,Eur.	45.76 mg
		8	Sugar Spheres (30-35 PHARM-A-SPHERES)	40.67 mg.
		9	Sucrose (Compressuc PS)	31.34 mg.
Duloxetine Caps. 60 mg (Net content of active ingredients 1500.00 kgs)	1 Number Capsule	10	Duloxetine Hydrochloride Ph,Eur.	68.71 mg.
		11	Sugar Spheres (30-35 PHARM-A-SPHERES)	61.00 mg.
		12	Sucrose (Compressuc PS)	47.00 mg.

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

Case No.	114 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred

Party Name	HELLO AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001685AM26
RA File Number	05AX04000971 AM26
Licence No and Date	0511033486/25/06/2025
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. To give chemical reaction indicating molecular weight of reactant and products and also yield of the reaction. 2. Manufacturing process and to give indigenous items to use in Annexure to Appendix-4E table with justification of wastage of raw materials. 3. To indicate the value of by-product/s formed during the process.	

Case No.	115 / NC/3/MEET/Apr/202627/1			
Case Status	Case Approved			
Party Name	VITAL LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026			
HQ File Number	HQRNORM APPLY 00001686AM26			
RA File Number	03AX04000194 AM26			
Licence No and Date	0311045089/25/06/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jul/202526/6 dated 31/07/2025 against advance authorization No. 0311040055 dated 31/12/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Artemether PH.I/ USP	1 kg.	1	Artemisinin	1.04 kg.
		2	Trimethyl Ortho Acetate	0.50 kg.
Artesunate PH.I	1 kg.	3	Artemisinin	0.80 kg.
Dihydro Artemisinin	1 kg.	4	Artemisinin	0.92 kg.

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

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

Case No.	116 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	VITAL LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001687AM26
RA File Number	03AX04000195 AM26
Licence No and Date	0311045090/25/06/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jul/202526/6 dated 31/07/2025 against advance authorization No. 0311040055 dated 31/12/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Artemether PH.I/ USP	1 kg.	1	Artemisinin	1.04 kg.

		2	Trimethyl Ortho Acetate	0.50 kg.
Artesunate PH.I	1 kg.	3	Artemisinin	0.80 kg.
Dihydro Artemisinin	1 kg.	4	Artemisinin	0.92 kg.

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

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

Case No.	117 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001690AM26
RA File Number	03AX04001519 AM26
Licence No and Date	0311045097/25/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxycycline Hyclate DR Tablets USP 100 mg 100 S((3,300 Bottles X 100 Per Bottles = 3,30,000 Tablets) (Total Weight of Export Product = 33.000 Kgs) (Exempts imported input/material weight inclusive of wastage = 42.105 Kgs))	1 Number Tablet	1	Doxycycline Hyclate USP	117.72 mg

Doxycycline Hyclate DR Tablets USP 150 mg 100 S((1,750 Bottles X 100 Per Bottles = 1,75,000 Tablets) (Total Weight of Export Product = 26.250 Kgs) (Exempts imported input/material weight inclusive of wastage = 33.492 Kgs)	1 Number Tablet	2	Doxycycline Hyclate USP	176.58 mg
Doxycycline Hyclate DR Tablets USP 200 mg 60 S((2,333 Bottles X 60 Per Bottles = 1,39,980 Tablets) (Total Weight of Export Product = 27.996 Kgs) (Exempts imported input/material weight inclusive of wastage = 35.720 Kgs))	1 Number Tablet	3	Doxycycline Hyclate USP	235.44 mg.

Note: NC also recommended making a new SION for the above export product.

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

Case No.	118 / NC/3/MEET/Apr/202627/1			
Case Status	Case Approved			
Party Name	VENUS REMEDIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026			
HQ File Number	HQRNORM APPLY 00001692AM26			
RA File Number	30AX04000179 AM26			
Licence No and Date	0511033498/25/06/2025			
Norms Committee Decision:				
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Oct/202526/9 dated 14/10/2025 against Advance Authorisation No. 3011006688 dt. 19/03/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Sugammadex solution for Injection 100 mg / ml (200 mg / 2 ml) (Each vial of 2 ml contains: Sugammadex Sodium equivalent to sugammadex 200 mg Hydrochloric acid 3.7% (to adjust pH) and/or Sodium hydroxide (to adjust pH) Water for Injections q.s)	1 Number	1	Sugammadex Sodium	239.326 mg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	119 / NC/3/MEET/Apr/202627/1
Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001697AM26
RA File Number	03AX04001461 AM26
Licence No and Date	0311045117/25/06/2025

Norms Committee Decision:

The firm was initially granted an Advance Authorisation for the export product “Alpha Hexyl Cinnamaldehyde and or Hexyl Cinnamic Aldehyde” under Para 4.07 of the Handbook of Procedures (HBP). However, as per Para 4.11(b) of the Foreign Trade Policy (FTP) 2023, products falling under the category of perfume or perfumery compounds are ineligible for authorisation under Para 4.07 and are mandatorily required to be processed under Para 4.06 of the HBP.

It was observed that the firm obtained the authorisation by **misdeclaring that its application was covered under the provisions of Para 4.07**, and has not furnished any technical justification/information for the export product. Accordingly, the Committee found no merit in fixing the norms and decided to reject the application.

The RA shall ensure that the said authorisation is regularized by recovery of applicable Customs duty along with interest. Further, the RA should also submit a report on how this authorisation was issued under Para 4.07 of HBP, to the Chairperson of the Norms Committee and to PC-4 Section, DGFT Headquarters.

The RA concerned may take further necessary action in line with the above decision of the Committee.

Case No.	120 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001714AM26
RA File Number	09AX04000238 AM26
Licence No and Date	0911009915/26/06/2025

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No. NC/3/MEET/Dec/202526/11 dated 18/12/2025 against Advance Authorisation No. 0911009506 dt. 24/04/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Teriparatide Injection 560 mcg/2.24 ml (250 mcg/ml) Fill Volume 2.54 ml)	1 Number	1	Teriparatide (Parathyroid Hormone (1-34) Human, Acetate)	616.0 mcg/Vial

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

Case No.	121 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026

HQ File Number	HQRNORM APPLY 00001715AM26
RA File Number	09AX04000271 AM26
Licence No and Date	0911009916/26/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Liraglutide Injection 18 mg/3 ml (6 mg/ml) 1x5's ((Each 3 ml contains Liraglutide 18 mg) Fill Volume- 3.3 ml)	1 Number	1	Liraglutide	19.8 mg/Vial
		2	3.0 ml Pre - Crimped Glass Siliconized Cartridge (Cartridge EZ-Fill Nexa VB 3ml)	Relevant, as per Packing Policy & General Notes.
		3	BD Vystra? Disposable Pen Body Subassembly with Purple Colour Dose Button (VYSTRAS BSA FR PL 284C BTN 2685C 50IU)	Relevant, as per Packing Policy & General Notes.
		4	BD Vystra? Disposable Pen Printed Cartridge Holder (VYSTRAS CARTRIDGE HOLDER PRINTED 0.6-15)	Relevant, as per Packing Policy & General Notes.
		5	BD Vystra? Disposable	Relevant, as

			Pen Cap (VYSTRA CAP PL MODERN 284C)	per Packing Policy & General Notes.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	122 / NC/3/MEET/Apr/202627/1
Case Status	Case Deferred
Party Name	SYNERGIA SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001757AM26
RA File Number	03AX04001477 AM26
Licence No and Date	0311045174/27/06/2025
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant information / documents from the firm.	

Case No.	123 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001769AM26
RA File Number	09AX04000304 AM26
Licence No and Date	0911009933/30/06/2025
Norms Committee Decision:	
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from	

the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ethyl-(2R,4S)-5-([1,1-biphenyl]-4-yl)-4-amino-2-methylpentanoate hydrochloride)	1 kg.	1	(2R,4S)-5-([1,1-biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid	1.21 kg.

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

Case No.	124 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001770AM26
RA File Number	09AX04000315 AM26
Licence No and Date	0911009934/30/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
(2S.3S.5s)-2-(2,6-Dimethyl phenoxy acetyl) amino-3-hydroxy-5-(tert-butoxy	1 kg	1	L-Phenylalanine	0.68 kg
		2	Tetra HydraFuran	1.30 kg

carbonyl) amino-1,6-diphenylhexane		3	Methane sulfonic acid	3.58 kg
		4	Sodium boro hydride	0.143 kg
		5	Di Tert.Butyl Di Carbonate	0.233 kg
		6	Di iso propyl ether	0.520 kg

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

Case No.	125 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	ANNORA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001774AM26
RA File Number	09AX04000184 AM26
Licence No and Date	0911009826/30/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Etravirine Tablets USP 200 MG. Composition: Each tablet contains Etravirine Premix 700 mg, it is equaling to Etravirine 200 mg.)	1 Number	1	Etravirine Premix IH	714 mg/Tablet

Etravirine Tablets USP 100 MG. Composition: Each tablet contains Etravirine Premix 350 mg, it is equaling to Etravirine 100 mg.)	1 Number	2	Etravirine Premix IH	357 mg/Tablet
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RA concerned may take further necessary action as per above decision of NC-III.

Case No.	126 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00001795AM26
RA File Number	03AX04001482 AM26
Licence No and Date	0311045230/30/06/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
FLUCORT N SKIN CREAM 0.025% (Pack Size 5 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 201.663 Gms.)	161330 Numbers	1	Fluocinolone Acetonide BP	205.70 gm.
FLUCORT SKIN CREAM 0.025% (Pack Size 15 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 604.988	161330 Numbers	2	Fluocinolone Acetonide BP	617.09 gm.

Gms.)				
FLUCORT N SKIN CREAM 0.025% (Pack Size 15 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 4537.500 Gms.)	1210000 Numbers	3	Fluocinolone Acetonide BP	4628.3 gm.
FLUCORT SKIN CREAM 0.025% (Pack Size 5 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 605.000 Gms.)	484000 Numbers	4	Fluocinolone Acetonide BP	617.10 gm.
FLUOCINOLONE CREAM (TDR) ET 0.025% (Pack Size 10 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 121.000 Gms.)	48400 Numbers	5	Fluocinolone Acetonide BP	123.42 gm.
CYNOZET CREAM 0.025% (Pack Size 5 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 121.000 Gms.)	96800 Numbers	6	Fluocinolone Acetonide BP	123.42 gm,
CYNOZET CREAM 0.025% (Pack Size 15 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 120.998 Gms.)	32266 Numbers	7	Fluocinolone Acetonide BP	123.42 gm.
SUPRICORT CREAM 0.025% (Pack Size 5 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 363.000 Gms.)	290400 Numbers	8	Fluocinolone Acetonide BP	370.26 gm.
SUPRICORT CREAM 0.025% (Pack Size 15 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 362.993 Gms.)	96798 Numbers	9	Fluocinolone Acetonide BP	370.25 gm.

SUPRICORT CREAM 0.025% (Pack Size 250 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 121.063 Gms.)	1937 Numbers	10	Fluocinolone Acetonide BP	123.48 gm.
SUPRICORT N CREAM 0.025% (Pack Size 5 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 121.000 Gms.)	96800 Numbers	11	Fluocinolone Acetonide BP	123.42 gm.
SUPRICORT N CREAM 0.025% (Pack Size 15 gms) (Net Wt. Of FLUOCINOLONE ACETONIDE BP is 120.998 Gms.)	32266 Numbers	12	Fluocinolone Acetonide BP	123.42 gm.
Flucort C Cream 0.01% (Pack Size 15 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 47.499 Gms)	31666 Numbers	13	Fluocinolone Acetonide BP	48.45 gm.
FLUCORT C OINTMENT 0.025% (Pack Size 15 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 302.494 Gms.)	80665 Numbers	14	Fluocinolone Acetonide BP	308.54 gm.
GLENCORT GEL 0.025 % (Pack Size 5 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 226.000 Gms.)	180800 Numbers	15	Fluocinolone Acetonide BP	230.52 gm.
GLENCORT GEL 0.025 % (Pack Size 30 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 242.010 Gms.)	32268 Numbers	16	Fluocinolone Acetonide BP	246.85 gm.
FLUCORT MZ SKIN OINTMENT 0.01% (Pack Size 15 gms) (Net	48399 Numbers	17	Fluocinolone Acetonide BP	74.05 gm.

Wt. of FLUOCINOLONE ACETONIDE BP is 72.599 Gms.)				
FLUCORT SKIN CREAM 0.025% (Pack Size 10 gms) (Net Wt. of FLUOCINOLONE ACETONIDE BP is 12.100 Gms.)	4840 Numbers	18	Fluocinolone Acetonide BP	12.34 gm.
RA concerned may take further necessary action as per above decision of NC-III.				

Case No.	127 / NC/3/MEET/Apr/202627/1
Case Status	Case Approved
Party Name	HPL ADDITIVES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202627/ 1 and 07/04/2026
HQ File Number	HQRNORM APPLY 00002735AM26
RA File Number	05AX04001422 AM26
Licence No and Date	0511034515/18/08/2025

Norms Committee Decision:

The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, **whichever is less**, as per the details indicated below:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Mikrofine ADST contains 55% N-N' Dinitroso pentamethylene tetramine (DNPT) and 5% Azodicarbonamide	1 kg.	1	Hexamine	0.470 kg.
		2	Sodium Nitrite	0.491 kg.
		3	Hydrazine Hydrate (100%)	0.003 kg.

		4	TGU (Technical Grade Urea)	0.007 kg.
RA concerned may take further necessary action as per above decision of NC-III.				