



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Jun/202627/4

DATED: 22/06/2026

Minutes of the Norms Committee-3 Meeting NC/3/MEET/Jun/202627/4 dated 22/06/2026 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 Raman Kumar, Joint DGFT	DGFT (HQ)
4	Smt. Skina Rani, FTDO	DGFT (HQ)

3. The Norms Committee has taken decisions only with respect to technical aspect/

wastage 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 Details and Decision(s):

Case No.	1 / NC/3/MEET/Jun/202627/4
Case Status	Case Rejected
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00000124AM26
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The representative of the firm appeared for the personal hearing and requested the fixation of norms in respect of Advance Authorisation No. 0910069488 dated 17/11/2020. The Norms Committee observed that the present application had been submitted under Para 4.06 of the HBP for the fixation of norms for the aforesaid authorisation, which was issued under Para 4.07 of the HBP. After detailed deliberation, the Committee decided to close the present application and call for a report from the concerned RA regarding the reasons for the non-fixation of norms in respect of Advance Authorisation No. 0910069488 dated 17/11/2020. The RA was further requested to furnish details of the imports and exports undertaken under the said authorisation to facilitate further examination of the matter.	

Case No.	2 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	SIGACHI INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00000805AM27
RA File Number	NA
Licence No and Date	NA
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 Drug Manufacturing Licence (DML) showing approved composition of export item.	

Case No.	3 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	SIGACHI INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00000806AM27
RA File Number	NA
Licence No and Date	NA
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 Drug Manufacturing Licence (DML) showing approved composition of export item.	

Case No.	4 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	AGROCEL INDUSTRIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001050AM27
RA File Number	NA
Licence No and Date	NA
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 chemistry, chemical reaction, Stichometric balance on molar basis with molecular weight and percentage yield for each step of reaction.	

Case No.	5 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	AGROCEL INDUSTRIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001054AM27
RA File Number	NA
Licence No and Date	NA
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 chemistry, chemical reaction, Stichometric balance on molar basis with molecular weight and percentage yield for each step of reaction.	

Case No.	6 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	AGROCEL INDUSTRIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001067AM27
RA File Number	NA
Licence No and Date	NA
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 chemistry, chemical reaction, Stichometric balance on molar basis with molecular weight and percentage yield for each step of reaction.	

Case No.	7 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	ORIENTAL AROMATICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001217AM27
RA File Number	NA
Licence No and Date	NA
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 purity of import and export item with Certificate of Analysis (CoA). 2. Molecular weight of import and export and percentage yield of conversion.	

Case No.	8 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	LINCOLN PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001324AM27
RA File Number	NA
Licence No and Date	NA
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. Description of export product not matching with Drug Manufacturing Licence (DML). Norms can not be fixed in its present form.	

Case No.	9 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00005879AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The case is under consideration, and the Technical Expert of DBT was requested to expedite his comments.	

Case No.	10 / NC/3/MEET/Jun/202627/4			
Case Status	Case Approved			
Party Name	PUROGENE LABS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026			
HQ File Number	HQRNORM APPLY 00006919AM25			
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 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.:-				
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Rilpivirine Hydrochloride (RIN-I) Intermediate	1 kg.	1	2-Thiouracil	0.57 kg.
		2	Diglyme	0.57 kg.

		3	Tetra Hydro Furan	0.48 kg.
		4	Methanol(Solvent)	6.23 kg.
		5	Caustic Soda Lye 48%	0.82 kg.
		6	4-Iodo-2, 6-Dimethyl Benzenamine	1.29 kg.

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

Case No.	11 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM REVIW00003500AM26
RA File Number	092404000369 AM19
Licence No and Date	0910066835/13/11/2018

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
(1R, 2S, 5R)-2-Isopropyl-5-methylcyclohexyl (2R, 5S)-5-(4-amino-2-oxopyrimidin-1(2H)-yl)-1,3-oxathiolane-2-	1 kg.	1	N,N-Dimethyl Formamide (DMF)	0.25 kg.
		2	Hexamethyl disilazane	0.730 kg.

carboxylate		3	Cytosine	0.478 kg.
		4	Triphosgene	0.500 kg.

Note:

1. The above norms are for regularisation and closure purposes only.
2. The Regional Authority (RA) shall not issue any further Authorisations on the basis of the above-mentioned norms on repeat basis.

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

Case No.	12 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM REVIW00003501AM26
RA File Number	092404000534 AM19
Licence No and Date	0910067129/04/02/2019

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
(1R, 2S, 5R)-2-Isopropyl-5-methylcyclohexyl (2R, 5S)-5-(4-	1 kg.	1	N,N-Dimethyl Formamide (DMF)	0.25 kg.

amino-2-oxopyrimidin-1(2H)-yl)-1,3-oxathiolane-2-carboxylate		2	Hexamethyl disilazane	0.730 kg.
		3	Cytosine	0.478 kg.
		4	Triphosgene	0.500 kg.

Note:

- I. The above norms are for regularisation and closure purposes only.
- II. The Regional Authority (RA) shall not issue any further Authorisations on the basis of the above-mentioned norms on repeat basis.

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

Case No.	13 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM REVIW00006048AM26
RA File Number	092404000605 AM20
Licence No and Date	0910068804/27/05/2020

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/202021/4 dated 12/02/2021 against advance authorization No. 0910067120 dated 31/01/2019, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Ulsanic 1G Effervescent Tablets	1 Number	1	Sucralfate (Aluminium	1.02 gm.

(Each Tablet Contains -1000 mg of Sucralfate)			Sucrose Sulphate with Aluminium Assay 18.8% and LOD 11.4%)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	14 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	LAZERHEAD LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM REVIW00004743AM26
RA File Number	09AA04012424 AM22
Licence No and Date	0911001950/26/11/2021

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.:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Ovaplant 250 mcg (Salmon Gonadotropin Releasing Hormone Analogue Implant)	18706 Numbers	1	Salmon Gonadorelin	4.723 gm.
Ovaprim 10 ml. Vial 20 mcg/ml (Salmon Gonadotropin Releasing Hormone Analogue Implant)	37976 Numbers	2	Salmon Gonadorelin	7.671 gm.

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

Case No.	15 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	STERLING AUXILIARIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM REVIW00005178AM25
RA File Number	03AX04002204 AM23
Licence No and Date	0311016388/15/07/2022
Norms Committee Decision: The committee considered the 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. Manufacturing process and complete chemistry with material balance.	

Case No.	16 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM REVIW00002872AM26
RA File Number	03AX04002399 AM23
Licence No and Date	0311017082/10/08/2022
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. Master-Batch formula for each export product.	

Case No.	17 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	LOZEN PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00008339AM24
RA File Number	03AX04004941 AM24
Licence No and Date	0311030679/05/02/2024

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Soothing Throat pops or Pops (Each Pop Contains 4821.68 Mg of Isomalt, 45 mg Wellmune Dispersible Powder & 58.82 mg of Acerola) (Net Content of Isomalt - 18750 kgs, of Wellmune Dispersible Powder - 174.991 kgs & of Acerola - 228.733 Kgs)	1 Number	1	Isomalt	4821.68 mg.
		2	Wellmune Dispersible Powder	45.00 mg.
Soothing Throat lozenges or Soothing Throat Drops or Lozenges or Drops (Each Lozenges Contains 3072 Mg of Isomalt & 27 mg of Wellmune Dispersible Powder) (Net Content of Isomalt - 109250 kgs & Wellmune Dispersible Powder - 960.205 Kgs)	1 Number	3	Isomalt	2092.50 mg.
		4	Wellmune Dispersible Powder	25.00 mg.
Cough Drops or Cough Lozenges or Lozenges or Drops (Each Lozenges Contains 3072	1 Number	5	Isomalt	1334.13 mg

Mg of Isomalt) (Net Content of Isomalt - 22000 kgs))				
Cough Relief Lozenges or Lozenges (Each Lozenges Contains 81.43 mg of Elderberry Extract & 10 Mg of Ivy Leaf Extract) (Net Content of Elderberry Extract - 1000 kgs & Ivy Leaf Extract - 122.085 kgs)	1 Number	6	Elderberry Dry Extract	Not recommended, No Master Batch Formula given.
		7	Ivy Leaf Extract	

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

Case No.	18 / NC/3/MEET/Jun/202627/4			
Case Status	Case Approved			
Party Name	PIRAMAL PHARMA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026			
HQ File Number	HQRNORM REVIW00006320AM25			
RA File Number	03AX04005442 AM24			
Licence No and Date	0311031542/27/02/2024			
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.:-				
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Vibegron (Gemtesa)	1 Number	1	Vibegron	77.187 mg./Tablet

Tablets 75 mg			(Average Potency 99.11%)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	19 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00009169AM24
RA File Number	03AX04005784 AM24
Licence No and Date	0311032244/16/03/2024

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.:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Sodium Iron EDTA	1 kg.	1	EDTA Acid	0.73 kg.

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

Case No.	20 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026			
HQ File Number	HQRNORM APPLY 00009206AM24			
RA File Number	03AX04005785 AM24			
Licence No and Date	0311032328/19/03/2024			
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.:-				
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
N-iodo SUCCINIMIDE	1 kg.	1	IODINE	0.74 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	21 / NC/3/MEET/Jun/202627/4
Case Status	Case Rejected
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002626AM25
RA File Number	05AX04001408 AM25
Licence No and Date	0511027294/21/08/2024
Norms Committee Decision:	
The Committee considered the application of the firm. It was observed that the firm had not furnished the specific information sought by the Committee during its meetings held on 27/03/2025 and 18/12/2025. In view of the non-submission of the requisite information, the Committee decided to reject the firm's application.	

Case No.	22 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	BHAGWATI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00003824AM25
RA File Number	08AX04001178 AM25
Licence No and Date	0811012998/23/10/2024

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
3-Amino-Pyrazole Carboxamidehemisulfate / (5-AminoPyrazole-4-Carboxamide Hemisulph	1 kg.	1	Tri Ethyl Ortho Formate	1.21 kg.
		2	Cyanoacetamide	0.74 kg.
		3	Morpholine	0.767 kg.
		4	Hydrazine Hydrate 80%	0.480 kg.

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

Case No.	23 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00004214AM25
RA File Number	05AX04002700 AM25
Licence No and	0511029003/19/11/2024

Date

Norms Committee Decision:

The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of the Representative of the firm, and after due deliberation, the Committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm or as applied, whichever is less:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Nepafenac Ophthalmic Suspension, 0.1% w/v Sterile Eye Drops, 5ml ((Each ml contains Nepafenac 1.0 mg (Equivalent to 625.000 Gram of Bulk Drug)	1 Number	1	Nepafenac (Micronized)	5.1 mg.
		2	1 Litre Polyelite El Powder Transfer Sterile Full Flat Ferrule Bag 4s 01elir Drawing No. Sffb1ir Hosokawa (Expo) (Packaging)	Deleted

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

Case No.	24 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00004279AM25
RA File Number	34AX04000704 AM25
Licence No and Date	3411005693/21/11/2024
Norms Committee Decision: The committee considered the 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 Purchase Order.
2. Copy of Shipping Bills.

Case No.	25 / NC/3/MEET/Jun/202627/4										
Case Status	Case Approved										
Party Name	DECCAN NUTRACEUTICALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026										
HQ File Number	HQRNORM REVIW00006138AM26										
RA File Number	02AX04000733 AM25										
Licence No and Date	0211008274/05/03/2025										
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.:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Item</td><td>Qty. allowed.</td></tr><tr><td>Nalbuphine Hydrochloride</td><td>1 kg.</td><td>1</td><td>Noroxymorphone Base</td><td>1.067 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.	Nalbuphine Hydrochloride	1 kg.	1	Noroxymorphone Base	1.067 kg.
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.							
Nalbuphine Hydrochloride	1 kg.	1	Noroxymorphone Base	1.067 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	26 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	VIJAYASRI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00000053AM26
RA File Number	09AX04001141 AM25

Licence No and Date 0911009349/02/04/2025

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/Apr/202627/2 dated 28/04/2026 against advance authorization No.0911008760 dated 06/01/2025, 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.
Tert-Butyl 2-((4R,6R)-6-(2-(2-(4-fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl)ethyl)-2,2-dimethyl-1,3-dioxane-4-yl)acetate (ATV-1) CAS No.125971-95-1)	11000 Kg.	1	Methyl Iso Butyryl Acetate (MIBA)(Liquid)	7150.0 kg.
		2	(4R,CIS)-1,1-Dimethylethyl-6-Cyano Methyl-2,2-Dimethyl-1,3-Dioxane-4-Acetate(Solid)	5830.0 kg.
		3	Tri Ethyl Amine (TEA)(Liquid)	2420.0 kg.
		4	Aniline Oil(Liquid)	4400.0 kg.
		5	Methylene Chloride (MDC)(Liquid)	14080.0 kg.
		6	Fluorobenzene (Liquid)	4950.0 kg.
		7	Acetone (Liquid)	4730.0 kg.
		8	Iso Propyl Alcohol (IPA) (Liquid)	27500.0 kg.

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

Case No.	27 / NC/3/MEET/Jun/202627/4
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM REVIW00006715AM26
RA File Number	05AX04004491 AM25
Licence No and Date	0511031702/02/04/2025
Norms Committee Decision: The Committee considered the firm's request for review of the ad hoc norms. However, it was observed that the norms given are based on the approved composition in the Drug Manufacturing Licence and wastage as per SION. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	28 / NC/3/MEET/Jun/202627/4			
Case Status	Case Approved			
Party Name	DECCAN NUTRACEUTICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026			
HQ File Number	HQRNORM REVIW00006139AM26			
RA File Number	02AX04000021 AM26			
Licence No and Date	0211008522/15/04/2025			
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.:-				
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Naltrexone Hydrochloride	1 kg.	1	Noroxymorphone Base	1.136 kg.

USP/PH.EUR				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	29 / NC/3/MEET/Jun/202627/4
Case Status	Case Rejected
Party Name	JUBILANT GENERICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM REVIW00006347AM26
RA File Number	05AX04000079 AM26
Licence No and Date	0511031904/15/04/2025
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 additional 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/Jun/202627/4
Case Status	Case Deferred
Party Name	NATURAL AND ESSENTIAL OILS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00000320AM26
RA File Number	07AX04000087 AM26
Licence No and Date	0711014206/17/04/2025
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. Copy of Shipping Bills
2. Copy of Bill of Entry
3. Certificate of Analysis (CoA) of import items.

Case No.	31 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00000379AM26
RA File Number	07AX04000114 AM26
Licence No and Date	0711014238/22/04/2025

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.:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Ascorbic Acid BP/Ascorbic Acid Ph.Eur/Ascorbic Acid USP / Ascorbic Acid	50 MT	1	Sodium Ascorbate	35.0 MT

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

Case No.	32 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00000562AM26
RA File Number	03AX04000465 AM26
Licence No and Date	0311043463/01/05/2025
Norms Committee Decision: The Committee considered the case as per agenda and it is observed that details given by the firm are confusing. Hence, it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant information / documents from the firm.	

Case No.	33 / NC/3/MEET/Jun/202627/4																
Case Status	Case Approved																
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026																
HQ File Number	HQRNORM APPLY 00000609AM26																
RA File Number	03AX04000503 AM26																
Licence No and Date	0311043518/05/05/2025																
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.:-																	
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Item</td><td>Qty. allowed.</td></tr><tr><td rowspan="2">Tocopheryl Acetate 405 IU Powder</td><td rowspan="2">1 kg.</td><td>1</td><td>Fatty Acid Distillate / Deodorised Distillate</td><td>6.13 kg.</td></tr><tr><td>2</td><td>Heptane - S</td><td>2.50 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.	Tocopheryl Acetate 405 IU Powder	1 kg.	1	Fatty Acid Distillate / Deodorised Distillate	6.13 kg.	2	Heptane - S	2.50 kg.
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.													
Tocopheryl Acetate 405 IU Powder	1 kg.	1	Fatty Acid Distillate / Deodorised Distillate	6.13 kg.													
		2	Heptane - S	2.50 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	34 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001326AM26
RA File Number	09AX04000229 AM26
Licence No and Date	0911009779/06/06/2025

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Velpatasvir Copovidone Premix (Containing NLT 50% Velpatasvir)	1 kg.	1	Methyl((S)-1-(2s,5s)-2-(9-(2-((2s,4s)-4-(Methoxymethyl) Pyrrolidin-2-Yl)1himidazol-5-Yl)1,11-Dihydroisochromeno (4,3:6,7) Naphtho (1,2-D) Imidazol-2-Yl)5-Methylpyrrolidin-1-Yl)-3-Methyl-1-Oxobutan-2-Yl) Carbamate)	0.51 kg.
		2	Acetic Acid Ethenyl Ester Polymer with 1-Ethenyl-2-Pyrrolidine, 1-Vinyl-2-Pyrrolidone Polymer with Vinyl Acetate (Copovidone))	0.51 kg.

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

Case No.	35 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	APITORIA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001359AM26
RA File Number	09AX04000237 AM26
Licence No and Date	0911009784/06/06/2025

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Sitagliptin Phosphate Anhydrous	1 kg.	1	N-Boc Tp Butanoic Acid (or) (R)-3-(tertbutoxycarbonylamino)-4-(2,4,5-trifluorophenyl) butanoic acid	0.81 kg.
		2	Methanol (Methyl Alcohol)	5.25 kg.

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

Case No.	36 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001424AM26
RA File Number	52AX04000071 AM26
Licence No and Date	5211014068/10/06/2025
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:

1. Complete and balanced chemical reactions with molecular weight and percentage yield on molar basis.
2. Material balance for each step.
3. Requirement and recovery of solvent at each step.

Case No.	37 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	BRAWN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001508AM26
RA File Number	05AX04000958 AM26
Licence No and Date	0511033337/16/06/2025

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Ciprofloxacin Tablets 250 mg (Off White, Elongated, Biconvex, Film Coated Tablet, Scored On One Side)	1 Number	1	Ciprofloxacin Hydrochloride USP (Faintly Yellowish To Light Yellow Crystals)	283.06 mg.
Ciprofloxacin Tablets 500 mg (Off White, Elongated, Biconvex, Film Coated Tablet,	1 Number	2	Ciprofloxacin Hydrochloride USP (Faintly Yellowish To	566.12 mg.

Scored On One Side)			Light Yellow Crystals)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	38 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001515AM26
RA File Number	52AX04000087 AM26
Licence No and Date	5211014419/16/06/2025
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: I. Complete and balanced chemical reactions w v ith molecular weight and percentage yield on molar basis. II. Material balance for each step. III. Requirement and recovery of solvent at each step.	

Case No.	39 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	APITORIA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001520AM26
RA File Number	09AX04000282 AM26
Licence No and Date	0911009831/16/06/2025
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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Sitagliptin Phosphate Anhydrous	1 kg.	1	N-BOC TP Butanoic Acid (or) (R)-3-(tertbutoxycarbonylamino) -4-(2,4,5-trifluorophenyl) butanoic acid)	0.81 kg.
		2	Methanol (Methyl Alcohol)	5.25 kg.

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

Case No.	40 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001605AM26
RA File Number	07AX04000327 AM26
Licence No and Date	0711014809/20/06/2025

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
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Calcium Gluconate (EP For Injection EP/Ph.Eur/JP/USP/BP/Powder)	1 kg.	1	Calcium Gluconate	1.09 kg.
Calcium Borogluconate	1 kg.	2	Calcium Gluconate	0.913 kg.
Calcium Glubionate (For Injection) / Calcium Glubionate	1 kg.	3	Calcium Gluconate	0.43 kg.

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

Case No.	41 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001647AM26
RA File Number	07AX04000518 AM26
Licence No and Date	0711014819/24/06/2025
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 and balanced chemical reaction showing molecular weight, percentage yield on molar basis. 2. By-product recovery and its commercial value. 3. Past Production/consumption data certified by Chartered Accountant.	

Case No.	42 / NC/3/MEET/Jun/202627/4
Case Status	Case Rejected
Party Name	SARNA CHEMICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM REVIW00006460AM26
RA File Number	52AX04000098 AM26
Licence No and Date	5211014633/25/06/2025
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 additional 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.	43 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	SYNERGIA SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00001757AM26
RA File Number	03AX04001477 AM26
Licence No and Date	0311045174/27/06/2025
Norms Committee Decision: The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of the Representative of the firm, and after due deliberation it was directed to firm to furnish the following information/documents for further consideration:- 1. Quantity of export made from import item No. 1 and 3 with documentary evidence along with Copy of Shipping Bills and Bill of Entry. 2. Quantity of export made from import item no. 2 and 3 for this particular licence with statement.	

Case No.	44 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026

HQ File Number	HQRNORM APPLY 00002450AM26																
RA File Number	31AX04000204 AM26																
Licence No and Date	3111005148/01/08/2025																
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:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Item</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Aminowel 5% Infusion 250 ml</td> <td rowspan="2">1 Number</td> <td>1</td> <td>L-ALANINE EP</td> <td>1.89 gm.</td> </tr> <tr> <td>2</td> <td>GLYCINE EP IP</td> <td>0.919 gm</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.	Aminowel 5% Infusion 250 ml	1 Number	1	L-ALANINE EP	1.89 gm.	2	GLYCINE EP IP	0.919 gm
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.													
Aminowel 5% Infusion 250 ml	1 Number	1	L-ALANINE EP	1.89 gm.													
		2	GLYCINE EP IP	0.919 gm													

Case No.	45 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	ROOPA INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002459AM26
RA File Number	09AX04000324 AM26
Licence No and Date	0911010165/01/08/2025
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 chemistry, chemical reaction, stichometric balance on molar basis with mol weight	

and percentage yield for each step of reaction

2. Recovery of solvent if any

3. How to arrive at the quantity of import asked on the basis of above details?

Case No.	46 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002478AM26
RA File Number	09AX04000480 AM26
Licence No and Date	0911010173/04/08/2025

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Pinsubet 6 mg. /ml. PEN 1X2'S (ORBI-CIP-GB)- Liraglutide Injection 18 mg/3 mL (6 mg/mL)((Each 3 mL contains Liraglutide 18 Mg)	1 Number	1	Liraglutide (API- (Water content 6.4% and NA 1.80%) = 8.2% %)	19.8 mg.
		2	3.0 ml. Pre - Crimped Glass Siliconized Cartridge (Cartridge EZ-Fill Nexa VB 3mL)	Relevant, as per Packing Policy and General Notes with accountability
		3	BD Vystr Disposable Pen Body Subassembly with Blue Colour Dose Button (VYSTR BSA FR PL 284C BTN 284C	Relevant, as per Packing Policy and General Notes.

			30IU)	
		4	BD Vystra Disposable Pen Printed Cartridge Holder (Vystra Cartridge Holder Printed 0.6-15)	Relevant, as per Packing Policy and General Notes with accountability
		5	BD Vystra Disposable Pen Cap (Vystra Cap Pl Modern 284C	Relevant, as per Packing Policy and General Notes with accountability.
Pinsubet 6 mg / ml. PEN 1X3'S ORBI-CIP-GB)- Liraglutide Injection 18 mg/3 mL (6 mg/mL)((Each 3 mL contains Liraglutide 18 Mg)	1 Number	6	Liraglutide (API- (Water content 6.4% and NA 1.80%) = 8.2 % %)	19.8 mg.
		7	3.0 mL Pre - Crimped Glass Siliconized Cartridge (Cartridge EZ-Fill Nexa VB 3mL)	Relevant, as per Packing Policy and General Notes with accountability.
		8	BD Vystr Disposable Pen Body Subassembly with Blue Colour Dose Button(VYSTR BSA FR PL 284C BTN 284C 30IU)	Relevant, as per Packing Policy and General Notes with accountability.
		9	BD Vystra Disposable Pen Printed Cartridge Holder (Vystra Cartridge Holder Printed 0.6-15)	Relevant, as per Packing Policy and General Notes with accountability.
		10	BD Vystra Disposable Pen	Relevant, as per

			Cap (Vystra Cap Pl Modern 284C	Packing Policy and General Notes with accountability.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	47 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002479AM26
RA File Number	09AX04000481 AM26
Licence No and Date	0911010174/04/08/2025

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
PLAOBES 6 mg / ml Pen Liraglutide Injection 18 mg /3 ml. (6 mg/ml) ((Each 3 ml contains Liraglutide 18 Mg) Fill Volume- 3.3 ml.	1 Number	1	Liraglutide (API- (Water content 6.4% and NA 1.80%) = 8.2%%)	19.8 mg.
		2	3.0 ml Pre - Crimped Glass Siliconized Cartridge (Cartridge EZ-Fill Nexa VB 3ml)	Relevant, as per Packing Policy and General Notes with accountability.

		3	BD Vystra Disposable Pen Body Subassembly with Dose Button (VYSTRA BSA FR PL 284C BTN 2685C 50 IU)	Relevant, as per Packing Policy and General Notes with accountability.
		4	BD Vystra Disposable Pen Printed Cartridge Holder (Vystra Cartridge Holderprinted 0.6-15)	Relevant, as per Packing Policy and General Notes with accountability.
		5	BD Vystra Disposable Pen Cap (Vystra CAP PL Modern 284C)	Relevant, as per Packing Policy and General Notes with accountability.

Note: NC also recommended to make a new SION for the export product.

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

Case No.	48 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002480AM26
RA File Number	09AX04000482 AM26
Licence No and Date	0911010175/04/08/2025
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.:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
PLAOBES 6 mg / ml Pen Liraglutide Injection 18 mg /3 ml. (6 mg/ml) ((Each 3 ml contains Liraglutide 18 Mg) Fill Volume- 3.3 ml.	1 Number	1	Liraglutide (API- (Water content 6.4% and NA 1.80%) = 8.2%%)	19.8 mg.
		2	3.0 ml Pre - Crimped Glass Siliconized Cartridge (Cartridge EZ-Fill Nexa VB 3ml)	Relevant, as per Packing Policy and General Notes with accountability.
		3	BD Vystra Disposable Pen Body Subassembly with Dose Button (VYSTRA BSA FR PL 284C BTN 2685C 50 IU)	Relevant, as per Packing Policy and General Notes with accountability.
		4	BD Vystra Disposable Pen Printed Cartridge Holder (Vystra Cartridge Holder printed 0.6-15)	Relevant, as per Packing Policy and General Notes with accountability
		5	BD Vystra Disposable Pen Cap (Vystra CAP PL Modern 284C)	Relevant, as per Packing Policy and General Notes with accountability.

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

Case No.	49 / NC/3/MEET/Jun/202627/4										
Case Status	Case Approved										
Party Name	TOPNOTCH CHEMICALS PVT LTD										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026										
HQ File Number	HQRNORM APPLY 00002482AM26										
RA File Number	03AX04002282 AM26										
Licence No and Date	0311046218/04/08/2025										
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/May/202627/3 dated 26/05/2026 against advance authorization No.0311045608 dated 11/07/2025 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="196 1018 1428 1220"> <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>Artemether</td><td>1 kg.</td><td>1</td><td>Artemisinin</td><td>1.04 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.	Artemether	1 kg.	1	Artemisinin	1.04 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Artemether	1 kg.	1	Artemisinin	1.04 kg.							

Case No.	50 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	TOPNOTCH CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002483AM26
RA File Number	03AX04002260 AM26
Licence No and Date	0311046219/04/08/2025
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/May/202627/3 dated 26/05/2026 against advance authorization No.0311046034 dated 29/07/2025 , 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.
Lumefantrine	1 kg.	1	9H FLUORENE	0.814 kg.
		2	Di N Butylamine	0.390 kg.
		3	Sodium Borohydride	0.040 kg.
		4	Para Chloro Benzaldehyde	0.336 kg.
		5	Di Methyl Formamide	0.555 kg.

Note: NC also recommended to make a new SION for the export product.

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

Case No.	51 / NC/3/MEET/Jun/202627/4
Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002493AM26
RA File Number	03AX04001543 AM26
Licence No and Date	0311046232/04/08/2025
Norms Committee Decision:	

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

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

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

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

Case No.	52 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002495AM26
RA File Number	03AX04002280 AM26
Licence No and Date	0311046235/04/08/2025

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 chemistry, chemical reaction, stoichiometric balance on molar basis with molecular weight and percentage yield for each step of reaction.

Case No.	53 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	ASENCE PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002497AM26
RA File Number	34AX04000416 AM26
Licence No and Date	3411006808/04/08/2025
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. Whether export item is sterile. 2. What is the difference between import and export item when both are showing as EP grade. 3. Step-wise process and technical justification for each step of manufacturing process.	

Case No.	54 / NC/3/MEET/Jun/202627/4	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026	
HQ File Number	HQRNORM APPLY 00002503AM26	
RA File Number	03AX04002077 AM26	
Licence No and Date	0311046266/05/08/2025	
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 Gel & Ointment (Nitroglycerin Ointment USP 2% 1 gm (Box of 48 SACHET) Wt: 960.00 Kgs (Net Cont: Nitroglycerin on Lactose	1 Number

	192 Kgs, Pharmalan USP 336 Kgs))	
2	Medical cream Gel & Ointment (Nitroglycerin Ointment USP 2% 30 gm1 Number Tube Wt: 780.00 Kgs (Net Cont: Nitroglycerin on Lactose 156 Kgs, Pharmalan USP 273 Kgs)	

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.	55 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002506AM26
RA File Number	03AX04002255 AM26
Licence No and Date	0311046271/05/08/2025
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/May/202526/3 dated 04/06/2025	

against advance authorization No.0311038037 dated 17/10/2024 , 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 Item	Qty. allowed.
Diclofenac Gel 3% 25g (DOFIDAZ) (Net Wt. of Sodium Hyaluronate is 12.10 Kgs.)	1 Number	1	Sodium Hyaluronate	1.61 gm.
Soliker 30 mg/g gel 90 gm ES / Diclofenac Gel 3% 90g (Net Wt. of Sodium Hyaluronate is 3.27 Kgs.)	1 Number	2	Sodium Hyaluronate	1.62 gm.
Diclofenac Gel 3% 50g DE (Net Wt. of Sodium Hyaluronate is 1.82 Kgs.)	1 Number	3	Sodium Hyaluronate	1.62 gm.
Soliker 30 mg/g gel 60 gms ES 60g / Diclofenac Gel 3% 60g (Net Wt. of Sodium Hyaluronate is 2.18 Kgs.)	1 Number	4	Sodium Hyaluronate	8.41 gm.

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

Case No.	56 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002516AM26
RA File Number	03AX04002241 AM26

Licence No and Date	0311046286/05/08/2025
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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/202425/17 dated 25/02/2026 against advance authorization No. 0311024513 dated 13/06/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50 mg) 50 ml vial ((Net content of exempted material is 1346.072 Kgs 30100 nos))	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50 mg) 100 ml vial ((Net content of exempted material is 3765.424 Kgs 42100 nos))	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50 mg) 250 ml vial ((Net content of exempted material is 1878.24 Kgs 8400 nos))	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50 mg) 500 ml vial ((Net content of exempted material is 2683.2 Kgs 6000 nos))	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 50ml vial ((Net content of exempted material is 1283.464 Kgs 30100 Nos))	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial ((Net content of exempted material is 5125.328 Kgs 60100 Nos))	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 250 ml vial ((Net content of exempted material is 3198 Kgs 15000	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial

Nos))				
PAN Ashoxy 3% (Oxytetracycline Injection 30 mg) 100 ml vial ((Net content of exempted material is 2566.928 Kgs 30100 Nos))	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200 mg) 50 ml vial ((Net content of exempted material IS 281.74 KGS & 30100 NOS))	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200 mg) 100 ml vial ((Net content of exempted materials is 563.72 kgs 30100 nos))	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200 mg) 250 ml vial ((Net content of exempted material is 1408.68 kgs 30100 nos))	1 Number	11	PROPYLENE GLYCOL	45.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 10 ml vial ((Net content of exempted material is 306.7792 Kgs 30100 Nos))	1 Number	12	PROPYLENE GLYCOL	10.40 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 50 ml vial ((Net content of exempted material is 1905.904 Kgs 37400 Nos))	1 Number	13	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 100ml vial ((Net content of exempted material is 6431.152 Kgs 63100 Nos))	1 Number	14	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 250 ml vial ((Net content of exempted material is 3822 Kgs 15000 Nos))	1 Number	15	PROPYLENE GLYCOL	260.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 500 ml vial ((Net content of exempted material is 3051.36 Kgs 6000 Nos))	1 Number	16	PROPYLENE GLYCOL	520.00 gm/Vial

Ashiver Forte (Ivermectin 10 mg and Clorsulon 100 mg Injection) 50 ml vial ((Net content of exempted material is 1543.287 Kgs 30100 nos))	1 Number	17	PROPYLENE GLYCOL	50.96 gm/Vial
Ashiver Forte (Ivermectin 10 mg and Clorsulon 100 mg Injection) 100 ml vial ((Net content of exempted material is 3099.096 Kgs 30100 nos))	1 Number	18	PROPYLENE GLYCOL	101.92 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100 mg) 50 ml vial ((Net content of exempted material is 156.52 Kgs 30100 Nos))	1 Number	19	PROPYLENE GLYCOL	5.20 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 100 ml vial ((Net content of exempted material is 313.04 Kgs 30100 Nos))	1 Number	20	PROPYLENE GLYCOL	10.40 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100 mg) 250 ml vial ((Net content of exempted material is 782.6 Kgs 30100 Nos))	1 Number	21	PROPYLENE GLYCOL	26.00 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200 mg) 50 ml vial ((Net content of exempted material is 313.04 Kgs 30100 nos))	1 Number	22	PROPYLENE GLYCOL	10.40 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200 mg) 100 ml vial ((Net content of exempted material is 938.08 Kgs 40100 nos))	1 Number	23	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200 mg) 250 ml vial ((Net content of exempted material is 785.2 Kgs 15100 nos))	1 Number	24	PROPYLENE GLYCOL	52.00 gm/Vial
Ashityl 5% (Tylosin Tartrate injection eq to Tylosin 50 mg) 50 ml vial ((Net	1 Number	25	PROPYLENE GLYCOL	10.40 gm/Vial

content of exempted material is 313.04 Kgs 30100 nos))				
Ashital 10% (Closantel 10% Inj) 100 ml vial ((Net content of exempted material is 1659.112 Kgs 30100 Nos))	1 Number	26	PROPYLENE GLYCOL	55.12 gm/Vial

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

Case No.	57 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002522AM26
RA File Number	07AX04000835 AM26
Licence No and Date	0711015275/05/08/2025

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/Apr/202425/2 dated 30/04/2024 against advance authorization No.0711008352 dated 22/06/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No	Import Items	Qty. allowed.
Bromocriptin Tablets 2.5 mg.	1 Number	1	Bromocriptin Mesylate BP/EP/IP/USP	2.924 mg.

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

Case No.	58 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002535AM26
RA File Number	03AX04002299 AM26
Licence No and Date	0311046328/06/08/2025

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/Apr/202526/1 dated 25/04/2025 against advance authorization No. 0311037113 dated 12/09/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ciclopirox Gel 0.77percent (Pack 30 gms) (Net wt. of Ciclopirox USP is 20.790 Kgs.)	1 Number	1	Ciclopirox USP	235.62 mg / pack
Ciclopirox Gel 0.77percent (Pack 45 Gms) (Net wt. of Ciclopirox USP is 17.325 Kgs.)	1 Number	2	Ciclopirox USP	352.967 mg / pack
Ciclopirox Gel 0.77percent (Pack 100 gms) (Net wt. of Ciclopirox USP is 50.05 Kgs.)	1 Number	3	Ciclopirox USP	785.00 mg / pack

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

Case No.	59 / NC/3/MEET/Jun/202627/4										
Case Status	Case Approved										
Party Name	GLENMARK PHARMACEUTICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026										
HQ File Number	HQRNORM APPLY 00002536AM26										
RA File Number	03AX04002192 AM26										
Licence No and Date	0311046329/06/08/2025										
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/202425/13 dated 07/01/2025 against advance authorization No. 0311035257 dated 07/07/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Colesevelam HCL OS 3.75 gm 30/ Colesevelam Hydrochloride for oral suspension 3.75 gm (Per Pack 30 Pouchs)</td><td>21000 Numbers Packs. (630000 Numbers Pouch)</td><td>1</td><td>Colesevelam Hydrochloride</td><td>2480.62 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Colesevelam HCL OS 3.75 gm 30/ Colesevelam Hydrochloride for oral suspension 3.75 gm (Per Pack 30 Pouchs)	21000 Numbers Packs. (630000 Numbers Pouch)	1	Colesevelam Hydrochloride	2480.62 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Colesevelam HCL OS 3.75 gm 30/ Colesevelam Hydrochloride for oral suspension 3.75 gm (Per Pack 30 Pouchs)	21000 Numbers Packs. (630000 Numbers Pouch)	1	Colesevelam Hydrochloride	2480.62 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	60 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002559AM26
RA File Number	05AX04001596 AM26

Licence No and Date	0511034353/07/08/2025
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.	61 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	APITORIA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002577AM26
RA File Number	09AX04000469 AM26
Licence No and Date	0911010216/08/08/2025

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Cefadroxil /Cefadroxil Monohydrate	1 kg.	1	7-Amino Des-Acetoxy Cephalosporanic Acid (7-ADCA)	0.643 kg.
		2	Penicillin G Amidase	0.004 kg.
		3	Methyl D-(-)-4-Hydroxyphenylglycinate (OR) D-(-)-4-Hydroxyphenylglycine Methyl ester	0.634 kg.
		4	Acetone	0.323 kg.

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

Case No.	62 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002585AM26
RA File Number	03AX04002331 AM26
Licence No and Date	0311046381/08/08/2025

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Clindamycin & Benzoyl Peroxide Gel 1 Percent/5 Percent (Pack Size 25 gm) ((Net Wt. of Import Item Sr. No. 1 is 3.50 Kgs. & Sr. No. 2 is 17.50 Kgs.))	14000 Numbers	1	Clindamycin Phosphate USP	3.57 kg.
		2	Hydrous Benzoyl Peroxide USP	17.85 kg.
Clindamycin & Benzoyl Peroxide Gel 1 Percent/ 5 Percent (Pack Size 35 gm) ((Net Wt. of Import Item Sr. No. 1 is 45.50 Kgs. & Sr. No. 2 is 227.50 Kgs.))	130000 Numbers	3	Clindamycin Phosphate USP	46.41 kg.
		4	Hydrous Benzoyl Peroxide USP	232.05 kg.
Clindamycin & Benzoyl Peroxide Gel 1 Percent/ 5 Percent (Pack Size 50 gm)	130000 Numbers	5	Clindamycin Phosphate USP	66.30 kg.

) ((Net Wt. of Import Item Sr. No. 1 is 65.00 Kgs. & Sr. No. 2 is 325.00 Kgs.))	20000 Numbers	6	Hydrous Benzoyl Peroxide USP	331.50 kg.
Clindamycin Phosphate Gel 1 Percent (Pack Size 30 gm) ((Net Wt. of Import Item Sr. No. 1 is 6.00 Kgs.))	20000 Numbers	7	Clindamycin Phosphate USP	6.12 kg.
Clindamycin Phosphate Gel 1 Percent (Pack Size 60 gm) ((Net Wt. of Import Item Sr. No. 1 is 12.00 Kgs.))		8	Clindamycin Phosphate USP	12.24 kg.
Adapalene & Benzoyl Peroxide Gel 0.1 Percent/ 2.5 Percent (Pack Size 45 gm) ((Net Wt. of Import Item Sr. No. 2 is 22.50)	20000 Numbers	9	Hydrous Benzoyl Peroxide USP	22.95 kg.
Clindamycin Phosphate Foam 1 Percent (Pack Size 50 gm) ((Net Wt. of Import Item Sr. No. 1 is 10.00 Kgs.))	20000 Numbers	10	Clindamycin Phosphate USP	10.20 kg.
Clindamycin Phosphate Foam 1 Percent (Pack Size 100 gm) ((Net Wt. of Import Item Sr. No. 1 is 20.00 Kgs.))	20000 Numbers	11	Clindamycin Phosphate USP	20.40 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	63 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026

HQ File Number	HQRNORM APPLY 00002589AM26
RA File Number	09AX04000484 AM26
Licence No and Date	0911010235/08/08/2025

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/202526/11 dated 18/12/2025 against advance authorization No. 0911009404 dated 09/04/2025, 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.
Sulindac	1 kg.	1	4-Fluoro Benzaldehyde	3.18 kg.
		2	Propionic Anhydride	3.15 kg.
		3	Sodium Propionate	2.32 kg.
		4	Methanol	3.14 kg.
		5	Acetic acid	5.71 kg.
		6	Cyano Acetic acid	1.16 kg.

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

Case No.	64 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002590AM26
RA File Number	31AX04000207 AM26

Licence No and Date	3111005163/08/08/2025
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 85 % in the reaction involved Methyl Ethyl Ketone (MEK). 2. Whether MEK can be recycled.	

Case No.	65 / NC/3/MEET/Jun/202627/4										
Case Status	Case Approved										
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026										
HQ File Number	HQRNORM APPLY 00002604AM26										
RA File Number	03AX04002424 AM26										
Licence No and Date	0311046416/11/08/2025										
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/Apr/202526/1 dated 25/04/2025 against advance authorization No. 0311029686 dated 27/12/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>ASHOXY 20% LA / OXYVET 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack size 50 ML vial((EACH VIAL CONTAINS 19 ML 2-pyrrolidone) (Nett Wt. of EXEMPTED</td><td>1086 kg.</td><td>1</td><td>2-Pyrrolidone</td><td>1141.13 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ASHOXY 20% LA / OXYVET 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack size 50 ML vial((EACH VIAL CONTAINS 19 ML 2-pyrrolidone) (Nett Wt. of EXEMPTED	1086 kg.	1	2-Pyrrolidone	1141.13 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
ASHOXY 20% LA / OXYVET 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack size 50 ML vial((EACH VIAL CONTAINS 19 ML 2-pyrrolidone) (Nett Wt. of EXEMPTED	1086 kg.	1	2-Pyrrolidone	1141.13 kg.							

MATERIAL IS 1086.8 Kgs) (55000 Nos))				
ASHOXY 20% LA / OXYVET 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack size 100 ML vial ((EACH VIAL CONTAINS 38ML 2-pyrrolidone) (Nett Wt. of EXEMPTED MATERIAL IS 2687.36 Kgs) (68000 Nos))	2687 kg.	2	2-Pyrrolidone	2821.73 kg.
ASHOXY 20% LA / OXYVET 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack size 250 ML vial ((EACH VIAL CONTAINS 95 ML 2-pyrrolidone) (Nett wt. of EXEMPTED MATERIAL IS 988 Kgs) (10000 Nos))	988 kg.	3	2-Pyrrolidone	1037.4 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	66 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002607AM26
RA File Number	05AX04001565 AM26
Licence No and Date	0511034405/11/08/2025
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/Nov/202425/10 dated 22/11/2024 against advance authorization No.0511025488 dated 14/05/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Moxifloxacin HCL and Dexamethasone Sodium Phosphate Eye Drops 0.5%w/v, 0.1% w/v, 5ml ((Each ml contain Moxifloxacin Base 5 mg. Equivalent to Moxifloxacin HCL 5.45mg & Dexamethasone Phosphate 1mg equi. to Dexamethasone Sodium Phosphate 1.1mg (Equi. to 6267.50 gm of Moxifloxacin HCL and 1265.00 gm of Dexamethasone Sodium Phosphate))	230000 Numbers	1	Moxifloxacin Hydrochloride	6580.875 gram.
		2	Dexamethasone Sodium Phosphate	1328.25 gram.

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

Case No.	67 / NC/3/MEET/Jun/202627/4
Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002615AM26
RA File Number	03AX04002296 AM26
Licence No and Date	0311046434/11/08/2025

Norms Committee Decision:

The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.

Case No.	68 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002623AM26
RA File Number	30AX04000326 AM26
Licence No and Date	3011007506/12/08/2025

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. Certificate of Analysis of import item showing percentage content of L-Arginine in the import item.
2. Master-Batch Formula for each export.

Case No.	69 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	APITORIA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002625AM26
RA File Number	09AX04000504 AM26
Licence No and Date	0911010246/12/08/2025

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.
Lurasidone Hydrochloride	1 kg.	1	(1R,2R)-1,2-Cyclohexanedimethanol	0.652 kg.
		2	Methanesulfonyl Chloride	1.56 kg.
		3	Piperazine derivative(or) 3-(1-Piperazinyl)-1,2-benzisothiazole hydrochloride	0.87 kg.
		4	Methanol	1.47 kg.
		5	Acetone	3.35 kg.
		6	Acetonitrile	5.25 kg.
		7	Carbon Enoanticromos (Activated carbon)	0.055 kg.
		8	Dicarboxymide	0.42 kg.

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

Case No.	70 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	EAST AFRICAN INDIA OVERSEAS
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026

HQ File Number	HQRNORM APPLY 00002636AM26													
RA File Number	05AX04001373 AM26													
Licence No and Date	0511034022/12/08/2025													
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:- <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">RO-Amiclox Ampicillin & Cloxacillin Capsules (10 X 10'S) (100 x 350000 = 35000000 Capsules) (250 mg + 250 mg)</td><td rowspan="2">1 Number</td><td>1</td><td>Ampicillin Trihydrate</td><td>294.032 mg.</td></tr> <tr> <td>2</td><td>Cloxacillin Sodium</td><td>277.95 mg.</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	RO-Amiclox Ampicillin & Cloxacillin Capsules (10 X 10'S) (100 x 350000 = 35000000 Capsules) (250 mg + 250 mg)	1 Number	1	Ampicillin Trihydrate	294.032 mg.	2	Cloxacillin Sodium	277.95 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
RO-Amiclox Ampicillin & Cloxacillin Capsules (10 X 10'S) (100 x 350000 = 35000000 Capsules) (250 mg + 250 mg)	1 Number	1	Ampicillin Trihydrate	294.032 mg.										
		2	Cloxacillin Sodium	277.95 mg.										

Case No.	71 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002663AM26
RA File Number	03AX04002376 AM26
Licence No and Date	0311046505/13/08/2025
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 Hexane content in export.
2. Percentage yield of reaction.

Case No.	72 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002695AM26
RA File Number	08AX04000782 AM26
Licence No and Date	0811015860/14/08/2025

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.
Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)	1 Number	1	Tranexamic acid (Injectable grade, US FDA approved)	1050 mg.

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

Case No.	73 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026

HQ File Number	HQRNORM APPLY 00002696AM26																		
RA File Number	08AX04000772 AM26																		
Licence No and Date	0811015864/14/08/2025																		
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/Jul/202526/6 dated 31/07/2025 against advance authorization No.0811013728 dated 07/01/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																			
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Magnesium Sulfate In Water for Injection (0.325 m Eq mg++/ml) 40 mg/ml 2g Total</td><td>1 Number</td><td>1</td><td>Magnesium Sulfate Heptahydrate</td><td>2.00 gm.</td></tr><tr><td>Magnesium Sulfate In Water for Injection (0.325 m Eq mg++/ml) 40 mg/ml 4g Total)</td><td>1 Number</td><td>2</td><td>Magnesium Sulfate Heptahydrate</td><td>4.00 gm.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Magnesium Sulfate In Water for Injection (0.325 m Eq mg++/ml) 40 mg/ml 2g Total	1 Number	1	Magnesium Sulfate Heptahydrate	2.00 gm.	Magnesium Sulfate In Water for Injection (0.325 m Eq mg++/ml) 40 mg/ml 4g Total)	1 Number	2	Magnesium Sulfate Heptahydrate	4.00 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Magnesium Sulfate In Water for Injection (0.325 m Eq mg++/ml) 40 mg/ml 2g Total	1 Number	1	Magnesium Sulfate Heptahydrate	2.00 gm.															
Magnesium Sulfate In Water for Injection (0.325 m Eq mg++/ml) 40 mg/ml 4g Total)	1 Number	2	Magnesium Sulfate Heptahydrate	4.00 gm.															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	74 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002702AM26
RA File Number	03AX04002514 AM26
Licence No and Date	0311046562/14/08/2025
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/May/202627/3 dated 26/05/2026 against advance authorization No.0311045822 dated 21/07/2025, 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.
Vibegron (Obgemsa / Gemtesa) 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.	75 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002703AM26
RA File Number	03AX04002515 AM26
Licence No and Date	0311046563/14/08/2025

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/May/202627/3 dated 26/05/2026 against advance authorization No.0311045822 dated 21/07/2025, 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.
Vibegron (Obgemsa / Gemtesa)	1 Number	1	Vibegron	76.50 mg.

Tablets 75 mg

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

Case No.	76 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002704AM26
RA File Number	30AX04000321 AM26
Licence No and Date	3011007533/14/08/2025

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.
MEROPENEM 500 mg Powder for Solution for Injection or Infusion(Each Vial Contains: Active Pharmaceutical Ingredients Meropenem Trihydrate equivalent to Meropenem Anhydrous...500 mg , Excipients : Anhydrous Sodium carbonate ph.Eur104 mg equivalent to 45.1mg of Sodium)	1 Number	1	Meropenem and Sodium Carbonate (Sterile Bulk)	672.6 mg/Vial
MEROPENEM 1000 mg Powder for Solution for Injection or Infusion(Each Vial	1 Number	2	Meropenem and Sodium Carbonate (Sterile Bulk)	1345 mg/Vial

Contains: Active Pharmaceutical Ingredients Meropenem Trihydrate equivalent to Meropenem Anhydrous...1000 mg , Excipients : Anhydrous Sodium carbonate ph.Eur ...208 mg equivalent to 90.2mg of Sodium)				
MEROPENEM 2 gm Powder for Solution for Injection or Infusion(Each Vial Contains: Active Pharmaceutical Ingredients Meropenem Trihydrate equivalent to 2000 mg Meropenem Anhydrous Excipients : Anhydrous Sodium carbonate ph.eur 416 mg equivalent to 180.4mg of Sodium)	1 Number	3	Meropenem and Sodium Carbonate (Sterile Bulk)	2690 mg/Vial

Note: NC also recommended to make a new SION for the export product.

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

Case No.	77 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	CIRON DRUGS AND PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002718AM26
RA File Number	03AX04002498 AM26
Licence No and Date	0311046581/18/08/2025
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/Apr/202627/2 dated 28/04/2026 against advance authorization No.0311040388 dated 13/01/2025, 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.
Bimatoprost Ophthalmic Solution 0.3 mg/ml - 3 ml (Each ml contains Bimatoprost 0.3 mg) (2,70,000 Nos) (Net Content :Bimatoprost - 0.243KGS)	1 Number	1	Bimatoprost	0.918 mg/3 ml. Vial

Note: NC also recommended to make a new SION for the export product.

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

Case No.	78 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002722AM26
RA File Number	03AX04002497 AM26
Licence No and Date	0311046588/18/08/2025
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 (Fluorouracil Cream 5% 15 Gm Tot Wt 3750 Kgs, Net Cont: 5-Fluorouracil 187.5 Kgs, STEARYL ALCO 562.5 Kgs, Propylene 431.25 Kgs, Methyl para 0.938, Propyl para 0.563, Tween 60 187.50, white petrolatum 806.25))	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.	79 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002733AM26
RA File Number	09AX04000532 AM26
Licence No and Date	0911010282/18/08/2025
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.
3-Bromomethyl-2-Cyclopropyl-4-(4-Fluorophenyl) Quinoline	1 kg.	1	Cyclopropyl methyl ketone	1.02 kg.
		2	Potassium Tert butoxide	2.04 kg.
		3	2-amino-4-Fluorobenzophenone	0.98 kg.

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

Case No.	80 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002738AM26
RA File Number	09AX04000531 AM26
Licence No and Date	0911010283/18/08/2025

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.
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Tert-Butyl [(4r. 6s)-6-Formyl-2,2-Dimethyl-1,3-Dioxan-4-Yl]Acetate (Aldehyde Side Chain) (Drug Intermediate)	1 kg.	1	tert.butyl - 2 [(4R, cis) - 6 - acetyloxy methyl - 2, 2 - dimethyl - 1, 3 - dioxane - 4 yl] acetate	1.575 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	81 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002760AM26
RA File Number	05AX04001674 AM26
Licence No and Date	0511034545/19/08/2025

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.0511031579 dated 25/03/2025, 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.
Picloxydine Ophthalmic Solution 10 ml Vial (Piclosept) - (Each ml contains 0.5 mg of Picloxydine Dihydrochloride)	1 Number	1	Picloxydine dihydrochloride 0.5 mg equivalent to Picloxydine base 0.434 mg	5.10 mg.

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

Case No.	82 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002761AM26
RA File Number	05AX04001675 AM26
Licence No and Date	0511034546/19/08/2025

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.
Inokain Eye Drops 0.4 Percent 5 ml (Each ml contains 4 mg of Benoxinate Hydrochloride)	1 Number Vial	1	Benoxinate HCL	20.4 mg/5 ml. Vial

Note: NC also recommended to make a new SION for the ophthalmic solution.

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

Case No.	83 / NC/3/MEET/Jun/202627/4
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Case Status	Case Deferred
Party Name	REACH GLOBAL INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002784AM26
RA File Number	31AX04000216 AM26
Licence No and Date	3111005186/20/08/2025
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 indicate the other material used with quantity export product.	

Case No.	84 / NC/3/MEET/Jun/202627/4										
Case Status	Case Approved										
Party Name	M CHEMICALS										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026										
HQ File Number	HQRNORM APPLY 00002788AM26										
RA File Number	52AX04000162 AM26										
Licence No and Date	5211016140/20/08/2025										
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.:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Schaeffers 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.	Schaeffers Acid (Highly Purified)	1 kg.	1	Beta Naphthol	0.80 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Schaeffers 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.	85 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM SPECIALITIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002798AM26
RA File Number	31AX04000228 AM26
Licence No and Date	3111005188/21/08/2025

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/Apr/202627/1 dated 07/04/2026 against advance authorization No. 3111004980 dated 17/06/2025, 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 Item	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.	86 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM SPECIALITIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026																			
HQ File Number	HQRNORM APPLY 00002802AM26																			
RA File Number	31AX04000231 AM26																			
Licence No and Date	3111005189/21/08/2025																			
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/Apr/202627/1 dated 07/04/2026 against advance authorization No. 3111004980 dated 17/06/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Item</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="3">2,6 Xylenol</td> <td rowspan="3">1 kg.</td> <td>1</td> <td>Phenol</td> <td>0.963 kg.</td> </tr> <tr> <td>2</td> <td>Methanol</td> <td>0.750 kg.</td> </tr> <tr> <td>3</td> <td>Catalyst (Katalco)</td> <td>0.004 kg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.	2,6 Xylenol	1 kg.	1	Phenol	0.963 kg.	2	Methanol	0.750 kg.	3	Catalyst (Katalco)	0.004 kg.
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.																
2,6 Xylenol	1 kg.	1	Phenol	0.963 kg.																
		2	Methanol	0.750 kg.																
		3	Catalyst (Katalco)	0.004 kg.																

Case No.	87 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	CHEMPLAST SANMAR LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002811AM26
RA File Number	04AX04000535 AM26
Licence No and Date	0411010246/21/08/2025
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.
Phenyl Guanidine Carbonate Monohydrate	1 kg.	1	Hydrogen Cyanamide 50%	0.565 kg.
		2	Aniline	0.626 kg.

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

Case No.	88 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002821AM26
RA File Number	07AX04000928 AM26
Licence No and Date	0711015437/22/08/2025

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. 0711011739 dated 05/07/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Magnesium Orotate	1 MT	1	Orotic Acid (Monohydrate)	0.990 MT

Calcium Orotate	1 MT	2	Orotic Acid (Monohydrate)	0.948 MT
Potassium Orotate	1 MT	3	Orotic Acid (Monohydrate)	0.944 MT
Zinc Orotate	1 MT	4	Orotic Acid (Monohydrate)	0.890 MT
Ferrous Orotate	1 MT	5	Orotic Acid (Monohydrate)	0.872 MT

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

Case No.	89 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002822AM26
RA File Number	07AX04000953 AM26
Licence No and Date	0711015442/22/08/2025

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.
Caffeine Citrate Injection 60mg/3ml (Equivalent to 30 mg of Caffeine Base) (46.875 KGS)	1 Number	1	Caffeine Anhydrous EP/BP/USP	33.0 mg

Caffeine Citrate Oral Solution 60 mg / 3 ml (Equivalent To 30 mg of Caffeine Base) (3.750KGS)	1 Number	2	Caffeine Anhydrous EP/BP/USP	30.6 mg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	90 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002866AM26
RA File Number	03AX04002549 AM26
Licence No and Date	0311046843/25/08/2025
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. Material balance in each step of purification with specification of import and intermediate stage. 2. Justification of 30% wastage (stage wise). 3. Certificate of Analysis of Import item from foreign supplier. 4. Item of import seems to be from waste chemical plant as such complete specification.	

Case No.	91 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002890AM26

RA File Number	07AX04000983 AM26			
Licence No and Date	0711015463/26/08/2025			
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/Sep/202526/8 dated 17/09/2025 against advance authorization No. 0711013540 dated 04/02/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Lisinopril 5 mg + Amlodipine 5 mg Tablets (21.00kgs))	1 Number Tablet	1	Lisinopril Dihydrate Ph. Eur	5.10 mg.
		2	Amlodipine Besilate BP	5.10 mg.
Lisinopril 10 mg + Amlodipine 5 mg Tablets (40.50kgs))	1 Number Tablet	3	Lisinopril Dihydrate Ph. Eur	10.2 mg.
		4	Amlodipine Besilate BP	5.10 mg.

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

Case No.	92 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002899AM26
RA File Number	30AX04000358 AM26
Licence No and Date	3011007589/26/08/2025
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.
Leucovorin Calcium Injection USP 50 mg/5 ml (Each ml contains: Leucovorin Calcium USP (INN. Calcium Folate) Equivalent to Leucovorin 10 mg Water for Injection USP q.s)	1 Number	1	Leucovorin Calcium	59.42 mg.
Leucovorin Calcium Injection USP 100 mg/10 ml (Each ml contains: Leucovorin Calcium USP (INN. Calcium Folate) Equivalent to Leucovorin 10 mg Water for Injection USP q.s)	1 Number	2	Leucovorin Calcium	118.84 mg.
Leucovorin Calcium Injection USP 300 mg/30 ml (Each ml Contains: : Leucovorin Calcium USP (Inn. Calcium Folate) Equivalent To Leucovorin10 mg Water For Injection USP Q.S)	1 Number	3	Leucovorin Calcium	340.323 mg.

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

Case No.	93 / NC/3/MEET/Jun/202627/4
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Case Status	Case Approved										
Party Name	AARTI INDUSTRIES LTD										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026										
HQ File Number	HQRNORM APPLY 00002920AM26										
RA File Number	03AX04002553 AM26										
Licence No and Date	0311046898/28/08/2025										
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.:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Para Nitro Aniline</td><td>1 kg.</td><td>1</td><td>Para Nitro Chloro Benzene</td><td>1.176 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Para Nitro Aniline	1 kg.	1	Para Nitro Chloro Benzene	1.176 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Para Nitro Aniline	1 kg.	1	Para Nitro Chloro Benzene	1.176 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	94 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	DECCAN NUTRACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002923AM26
RA File Number	02AX04000416 AM26
Licence No and Date	0211009403/28/08/2025
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:-	

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Nalbuphine Hydrochloride	1 kg.	1	Noroxymorphone Base	1.067 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	95 / NC/3/MEET/Jun/202627/4			
Case Status	Case Approved			
Party Name	JUBILANT GENERICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026			
HQ File Number	HQRNORM APPLY 00002932AM26			
RA File Number	05AX04001859 AM26			
Licence No and Date	0511034778/29/08/2025			
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.:-				
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Zopiclone Tablet 7.5mg	1 Number	1	Zopiclone Ph.Eur	7.53 mg/Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	96 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved

Party Name	HONOUR LAB LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026													
HQ File Number	HQRNORM APPLY 00002947AM26													
RA File Number	09AX04000566 AM26													
Licence No and Date	0911010368/01/09/2025													
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/Nov/202526/10 dated 14/11/2025 against advance authorization No. 0911008057 dated 27/09/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Ethyl-(2R,4S)-5-([1,1-biphenyl]-4-yl)-4-amino-2-methylpentanoate hydrochloride</td><td>1 kg.</td><td>1</td><td>(2R,4S)-5-([1,1-biphenyl]-4-yl)-4-((tert-butoxycarbonyl)amino)-2-methylpentanoic</td><td>1.21 kg.</td></tr></table>					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	1.21 kg.
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	1.21 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	97 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002963AM26
RA File Number	03AX04002773 AM26
Licence No and Date	0311046962/01/09/2025
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.:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Latanoprost Eye Drops 2.5 ml (Latanoprost 0.005% Eye Drops 2.5 ml) ((Each Vial Contains Latanoprost 0.125 mg Net Wt of Bulk Drug is 80.750 Grams))	646000 Vials	1	Latanoprost	82.365 gm.
Latanoprost 0.005% + Timolol 0.5% Eye Drops. 2.5 ml ((Each Vial Contains Latanoprost 0.125 mg Net Wt of Bulk Drug is 50.375 Grams))	403000 vials	2	Latanoprost	51.383 gm.

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

Case No.	98 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002967AM26
RA File Number	07AX04000996 AM26
Licence No and Date	0711015496/01/09/2025

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. For export item No. 7 (Calcium Magnesium Lactate Gluconate). As per manufacture process

given import item Glucono Delta Lactone is not shown in the process. Please clarify and give the revised manufacturing process and details.

2. Certificate of Analysis (CoA) of import item from foreign supplier indicating percentage purity and copies of Bill of Entry (since for some export item purity of imported item shown as 90 per cent)

Case No.	99 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002976AM26
RA File Number	09AX04000534 AM26
Licence No and Date	0911010379/02/09/2025

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Ascorbic Acid 50 mg Tablets (Pack Size 28 No of Packs 32143)	1 Number	1	Ascorbic Acid PH EUR CEP	51.00 mg/Tablet
Ascorbic Acid 100 mg Tablets (Pack Size 28 No of Packs 32143)	1 Number	2	Ascorbic Acid PH EUR CEP	102 mg/Tablet
Ascorbic Acid 200 mg Tablets (Pack Size 28 No of Packs 32143)	1 Number	3	Ascorbic Acid PH EUR CEP	204 mg/Tablet
Ascorbic Acid 500 mg Tablets	1 Number	4	Ascorbic Acid	510 mg/Tablet

(Pack Size 28 No of Packs 64286)			PH EUR CEP	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	100 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	PROCTER & GAMBLE HEALTH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002978AM26
RA File Number	03AX04002788 AM26
Licence No and Date	0311046999/02/09/2025

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.:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Thiamine Disulfide	1 kg.	1	Thiamine HCL	1.4199 kg.

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

Case No.	101 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	STERMONE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026

HQ File Number	HQRNORM APPLY 00002981AM26			
RA File Number	34AX04000468 AM26			
Licence No and Date	3411006905/02/09/2025			
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/May/202627/3 dated 26/05/2026 against advance authorization No. 3411006764 dated 23/07/2025, 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:-				

Case No.	102 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	LA CHANDRA PHARMALAB PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002983AM26
RA File Number	08AX04000917 AM26
Licence No and Date	0811016028/02/09/2025
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 showing molecular weight and	

percentage of yield on molar basis.
 II. Copy of Technical Literature/Justification for low yield of 21% in last stage of flow-charts.

Case No.	103 / NC/3/MEET/Jun/202627/4													
Case Status	Case Approved													
Party Name	SHREE CHEMOPHARMA ANKLESHWAR PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026													
HQ File Number	HQRNORM APPLY 00002986AM26													
RA File Number	34AX04000447 AM26													
Licence No and Date	3411006912/02/09/2025													
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:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Item</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>5 Nitro Salicylic Acid</td> <td>1 kg.</td> <td>1</td> <td>Ortho Chloro Benzoic Acid (99% Minimum)</td> <td>1.221 kg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.	5 Nitro Salicylic Acid	1 kg.	1	Ortho Chloro Benzoic Acid (99% Minimum)	1.221 kg.
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.										
5 Nitro Salicylic Acid	1 kg.	1	Ortho Chloro Benzoic Acid (99% Minimum)	1.221 kg.										

Case No.	104 / NC/3/MEET/Jun/202627/4			
Case Status	Case Deferred			
Party Name	SHILPA PHARMA LIFESCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026			
HQ File Number	HQRNORM APPLY 00002991AM26			
RA File Number	07AX04000948 AM26			

Licence No and Date	0711015519/02/09/2025
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 on molar basis for each step based on present data on conversion. 2. Production/Consumption data for the last three years certified by Chartered Accountant.	

Case No.	105 / NC/3/MEET/Jun/202627/4													
Case Status	Case Approved													
Party Name	SUPERFORM CHEMISTRIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026													
HQ File Number	HQRNORM APPLY 00002993AM26													
RA File Number	03AX04002468 AM26													
Licence No and Date	0311047022/03/09/2025													
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.:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Item</td><td>Qty. allowed.</td></tr><tr><td>Phenyl Isocyanate</td><td>1 kg.</td><td>1</td><td>Aniline</td><td>0.823 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.	Phenyl Isocyanate	1 kg.	1	Aniline	0.823 kg.
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.										
Phenyl Isocyanate	1 kg.	1	Aniline	0.823 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	106 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00002995AM26
RA File Number	03AX04002807 AM26
Licence No and Date	0311047017/03/09/2025

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/Jul/202526/6 dated 31/07/2025 against advance authorization No. 0311040145 dated 06/01/2025, 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.
Lampy-250 Capsule. Ampicillin Capsule BP 250 Mg. (Each Capsule Containing Ampicillin Trihydrate Equivalent to 250 mg. Ampicillin Base. Net content of Import/Exempt Material used in Export Product 1) Ampicillin Trihydrate BP (Compacted)-2018.539 Kg (Excl. 2 % Wastage))	1 Number	1	Ampicillin Trihydrate BP Compacted	294.5 mg.
Lampy-500 Capsule. Ampicillin Capsule BP 500 mg. (Each Capsule Containing Ampicillin Trihydrate Equivalent to 500 mg. Ampicillin Base. Net content of Import/Exempt Material Used In Export Product 1) Ampicillin Trihydrate BP (Compacted) -1155.411 Kg (Excl. 2% Wastage))	1 Number	2	Ampicillin Trihydrate BP Compacted	589.0 mg.
Lampyklox Capsule. Ampicillin	1 Number	3	Ampicillin Trihydrate	294.5 mg.

Trihydrate and Cloxacillin Sodium Capsules (250 mg + 250 mg) (Each Capsule Contains Ampicillin Trihydrate Equivalent to 250 mg of Ampicillin and Cloxacillin Sodium Equivalent To 250 mg Cloxacillin. Consumes Qty 1) Ampicillin Trihydrate BP (Compacted) - 1606.736 kg (Excl. 2% Wastage))			BP Compacted	
Lampyklox Dry Syrup. Ampicillin Trihydrate and Cloxacillin Sodium Suspension ((Each 5 ml Reconstituted Suspension Contains Ampicillin Trihydrate BP Equivalent to Ampicillin BP 125 mg). Net Content of Import / Exempt Material Used in Export Product 1) Ampicillin Trihydrate BP (Compacted)- 121.275 kgs (Excl 2% Wastage)) 100 ml Bottle.	1 Number Bottle	4	Ampicillin Trihydrate BP Compacted	2945.0 mg.

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

Case No.	107 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00003018AM26
RA File Number	52AX04000164 AM26
Licence No and Date	5211016505/03/09/2025
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/May/202627/3 dated 26/05/2026 against advance authorization No. 5211007280 dated 06/02/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Heterocyclic Compounds With Nitrogen atom with an unfused pyrazole ring with hydrogenated in the structure: 4-{1-[(2S)-2-Aminopropyl]-1-H-Pyrazole-3-yl}-2-Chlorobenzonitrile)	1 kg.	1	1(1-(2-Tetrahydropyranyl)-1H Pyrazole-5-Boronic Acid Pinacol Ester (1-(Tetrahydro 2H Pyran 2yl)-5-(4,4,5,5 Tetramethyl 1,3,2 Dioxaborolane-2-Yl)-1h-Pyrazole))	1.50 kg.
		2	4-Bromo-2-Chloro Benzonitrile	1.165 kg.
		3	2-Amino-1-Propanol (S-(+)-2-Amino-1-Propanol) ((S)-2-aminopropan-1-ol (L-Alininol)	0.46 kg.
		4	Di Tert Butyl Dicarbonate	1.34 kg.
		5	Di-isopropyl azodicarboxylate	1.034 kg.
		6	Triphenylphosphine	1.89 kg.

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

Case No.	108 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	STERICON PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00003027AM26
RA File Number	07AX04000793 AM26
Licence No and Date	0711015524/03/09/2025

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. Copy of Drug Manufacturing Licence (DML) for each export item showing approved composition of each export item.
2. Copy of Master-Batch Formula for each export item.
3. Certificate of Analysis (CoA) of import item from Foreign Supplier.
4. Net content of import item in each export and wastage claimed thereon.

Case No.	109 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	NASENSE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00003034AM26
RA File Number	09AX04000517 AM26
Licence No and Date	0911010403/04/09/2025

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 chemistry, chemical reaction, stoichiometric balance on molar basis with molecular weight and percentage yield for each step of reaction.

Case No.	110 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00003039AM26
RA File Number	52AX04000165 AM26

Licence No and Date	5211016542/04/09/2025			
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/Apr/202627/1 dated 07/04/2026 against advance authorization No. 5211008490 dated 13/06/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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.	111 / NC/3/MEET/Jun/202627/4
Case Status	Case Deferred
Party Name	PANVO ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00003044AM26
RA File Number	04AX04000591 AM26
Licence No and Date	0411010313/04/09/2025
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 chemistry, chemical reaction, stoichiometric balance on molar basis with molecular weight and percentage yield for each step of reaction.

Case No.	112 / NC/3/MEET/Jun/202627/4
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202627/ 4 and 22/06/2026
HQ File Number	HQRNORM APPLY 00003056AM26
RA File Number	08AX04000947 AM26
Licence No and Date	0811016047/04/09/2025

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:-

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed.
Sucralfate Tablets USP 1 gm (Active Ingredient: Sucralfate USP - Net Wt. 37490.800 Kgs))	1 Number	1	Sucralfate USP	1020 mg.
		2	Corn Starch NF (Maize Starch B)	76.5 mg.
		3	Magnesium Stearate PH.E/NF/JP	12.0 mg.

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