



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

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Meeting No -NC/3/MEET/Sep/202526/8

Meeting Date -17/09/2025

Minutes of the Norms Committee-3 Meeting No.NC/3/MEET/Aug/202526/7 dated 17/09/2025 under the Chairmanship of Shri Rakesh Kumar, Addl. DGFT for considering the cases/issues under Duty Exemption Scheme (Chapter-4) of the Foreign Trade Policy, 2023 pertaining to Chemical and Allied products falling under Chapter 29 and 30.

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

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

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

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

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

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Sep/202526/8																
Case Status	Case Approved																
Party Name	FINE ORGANIC INDUSTRIES LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025																
HQ File Number	HQRNORM APPLY 00001243AM26																
RA File Number	NA																
Licence No and Date	NA																
Norms Committee Decision:																	
The Committee considered the case as per the agenda and taking cue from the earlier decision for the same export product/import item in the meeting No.NC/3/MEET/Jan/202425/16 dated 27.01.2025 against DGFT (HQ) File No. HQNORMAPPLY00005602AM25, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">MONOGLYCERIDE (PS)</td><td rowspan="2">1 kg.</td><td>1</td><td>Hydrogenated Palm Stearin</td><td>0.872 kg.</td></tr><tr><td>2</td><td>Refined Glycerine</td><td>0.222 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MONOGLYCERIDE (PS)	1 kg.	1	Hydrogenated Palm Stearin	0.872 kg.	2	Refined Glycerine	0.222 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
MONOGLYCERIDE (PS)	1 kg.	1	Hydrogenated Palm Stearin	0.872 kg.													
		2	Refined Glycerine	0.222 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	2 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	CYKLO PHARMA CHEM PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM REVIW00003152AM25
RA File Number	032404000318 AM04
Licence No and Date	0310204913/29/05/2003
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 revision 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 Items	Qty. allowed.
Allantoin	1 kg.	1	Glyoxalic Acid 50%	1.05 kg.

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

Case No.	3 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM REVIW00002300AM25
RA File Number	092404000413 AM12
Licence No and Date	0910050238/15/12/2011

Norms Committee Decision:

The representative of the firm appeared for the personal hearing and presented submissions before the Committee. The Committee carefully examined the explanation furnished. However, it was observed that the firm failed to provide a satisfactory justification for the proposed enhancement of norms. Accordingly, the Committee decided to fix the norms for the two inputs as under, taking cue from the earlier decision in respect of the same export product in NC3/MEET/Jun/202122/2 dated 02.07.2021 against Authorisation No. 0910051360 dated 21.02.2021:

Export Product	Qty	Sl No	Import items	Qty allowed
RACTOPAMINE HCL	1 kg	1	(RS) 4-(2-amino-1-hydroxy ethyl) phenol HCL- CAS No 770-05-8	0.446 kg
			4(4-HYDROXY PHENYL)-2-	0.70 kg

			BUTANONE -CAS 5471-51-2	
It was further noted that the firm had sought authorisation for 11 inputs, but failed to provide adequate justification for 9 of them. This constitutes a prima facie case of misdeclaration on the part of the firm. In view of the above, the Committee directed the concerned RA to initiate appropriate enforcement action against the firm for misdeclaration and to furnish a detailed action-taken report to Headquarters. A copy of the decision be sent to PC-4 for appropriate action.				

Case No.	4 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	WEXFORD LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM REVIW00003782AM25
RA File Number	072404000120 AM18
Licence No and Date	0710111992/09/08/2017
Norms Committee Decision: The firm was called for Personal Hearing on 17/09/2025through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for Personal Hearingwith relevant documents/information.	

Case No.	5 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	ORGANIC INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM REVIW00005762AM25
RA File Number	06AA04003603 AM22
Licence No and Date	0611000533/02/07/2021
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed that export product applied by the firm pertains to Norms Committee-6, therefore, it has been decided that the application of the firm may	

be transferred to Norms Committee-6 for revision of ad-hoc norms.

Case No.	6 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM REVIW00005721AM25
RA File Number	03AX04000822 AM23
Licence No and Date	0311014992/25/05/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical reaction indicating molecular weight of both reactant and the products with yield of the reaction. 2. Stoichiometric material balance on a molar basis and to give value of by product Methanol obtained during the reaction. 3. Concentration of the ammonia and aqueous solution and accordingly, calculation of requirement of both the chemical. 4. Copy of Bill of Entry.	

Case No.	7 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM REVIW00004127AM25
RA File Number	03AX04002151 AM23
Licence No and Date	0311016241/11/07/2022
Norms Committee Decision: The firm was called for Personal Hearing on 17.09.2025 through Video Conference. The firm vide e-mail dated 16.09.2025 has informed that their technical expert is not available and requested to postpone the Personal Hearing. The Committee has decided to grant one more opportunity to the firm for Personal Hearing with relevant documents/information.	

Case No.	8 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00001993AM23
RA File Number	34AX04000353 AM23
Licence No and Date	3411002522/12/07/2022

Norms Committee Decision:

The Committee considered the case as per the agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aug/202526/7 dated 22/08/2025 against advance authorization No.3411003278 dated 24/01/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxycycline Caps. USP 75 mg.	1 Number	1	Doxycycline Monohydrate USP	82.26 mg
		2	Microcrystalline Cellulose (Avicel PH 301)	88.874 mg.
		3	Sodium Starch Glycolate (Type A) (EXPLOTAB)	12.75 mg.
		4	Povidone (Kollidon30 LP)	6.00 mg.
		5	Microcrystalline Cellulose (Avicel PH 200 LM)	15.00 mg.
		6	Colloidal Silicon Dioxide (Aerosil 200 Pharma)	1.088 mg.
		7	Magnesium Stearate (Vegetable Source)	2.25 mg.
Doxycycline Caps. USP 100 mg	1 Number	8	Doxycycline Monohydrate USP	109.68 mg.

		9	Microcrystalline Cellulose (Avicel PH 301)	118.498 mg.
		10	Sodium Starch Glycolate (Type A) (EXPLOTAB)	17.00 mg.
		11	Povidone (Kollidon30 LP)	8.00 mg.
		12	Microcrystalline Cellulose (Avicel PH 200 LM)	20.00 mg.
		13	Colloidal Silicon Dioxide (Aerosil 200 Pharma)	1.45 mg.
		14	Magnesium Stearate (Vegetable Source)	3.00 mg.

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

Case No.	9 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM REVIW00005722AM25
RA File Number	03AX04002261 AM23
Licence No and Date	0311016368/15/07/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. Chemical reaction indicating molecular weight of both reactant and the products with yield of the reaction. II. Stoichiometric material balance on a molar basis and to give value of by product Methanol obtained during the reaction. III. Concentration of the ammonia and aqueous solution and accordingly, calculation of requirement of both the chemical.	

IV. Copy of Bill of Entry.

Case No.	10 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00002358AM23
RA File Number	34AX04000398 AM23
Licence No and Date	3411002586/29/07/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxepin HCL Capsules 10 mg (net content of active ingredients = 28.00 kgs)	1 Number	1	Doxepin Hydrochloride	11.353 mg.
		2	Microcrystalline cellulose (Avicel PH 302)	44.971 mg.
		3	Sodium Lauryl Sulfate (Kolliphor SLS Fine)	0.080 mg.
		4	Pregelatinized Starch (Starch 1500 Partially Pregelatinized Maize Starch)	7.332 mg.
		5	Colloidal silicon dioxide (Aerosil 200 Pharma)	1.32 mg.
		6	Magnesium Stearate	0.496 mg.
Doxepin HCL Capsules 25	1 Number	7	Doxepin Hydrochloride	28.384 mg.

mg (net content of active ingredients = 70.00 kgs)		8	Microcrystalline cellulose (Avicel PH 302)	112.427 mg.
		9	Sodium Lauryl Sulfate (Kolliphor SLS Fine)	0.200 mg.
		10	Pregelatinized Starch (Starch 1500 Partially Pregelatinized Maize Starch	18.33 mg.
		11	Colloidal silicon dioxide (Aerosil 200 Pharma)	3.30 mg.
		12	Magnesium Stearate(Magnesium Stearate)	1.24 mg.
Doxepin HCL Capsules 50 mg (net content of active ingredients = 140.00 kgs)	1 Number	13	Doxepin Hydrochloride	56.766 mg.
		14	Microcrystalline cellulose (Avicel PH 302)	91.592 mg
		15	Sodium Lauryl Sulfate (Kolliphor SLS Fine)	1.313 mg.
		16	Pregelatinized Starch (Starch 1500 Partially Pregelatinized Maize Starch)	19.445 mg.
		17	Colloidal silicon dioxide (Aerosil 200 Pharma)	3.50 mg.
		18	Magnesium Stearate	1.312 mg.
Doxepin HCL Capsules 75 mg (net content of active ingredients = 90.00 kgs)	1 Number	19	Doxepin Hydrochloride	85.152 mg.
		20	Microcrystalline cellulose (Avicel PH 302)	137.388 mg.
		21	Sodium Lauryl Sulfate (Kolliphor	1.969 mg.

			SLS Fine)	
		22	Pregelatinized Starch (Starch 1500 Partially Pregelatinized Maize Starch)	29.168 mg.
		23	Colloidal silicon dioxide (Aerosil 200 Pharma)	5.25 mg.
		24	Magnesium Stearate	1.969 mg.
Doxepin HCL Capsules 100 mg (net content of active ingredients = 120.00 kgs)	1 Number	25	Doxepin Hydrochloride	113.538 mg.
		26	Microcrystalline cellulose (Avicel PH 302)	183.185 mg.
		27	Sodium Lauryl Sulfate (Kolliphor SLS Fine)	2.625 mg.
		28	Pregelatinized Starch (Starch 1500 Partially Pregelatinized Maize Starch)	38.890 mg.
		29	Colloidal silicon dioxide (Aerosil 200 Pharma)	7.00 mg.
		30	Magnesium Stearate	2.625 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	11 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003251AM23
RA File Number	34AX04000590 AM23

Licence No and Date	3411002800/21/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxepin HCL Capsules 10 mg (net content of active ingredients = 28.00 kgs)	1 Number	1	Doxepin Hydrochloride	11.353 mg.
		2	Microcrystalline cellulose (Avicel PH 302)	44.971 mg.
		3	Sodium Lauryl Sulfate (Kolliphor SLS Fine)	0.080 mg.
		4	Pregelatinized Starch (Starch 1500 Partially Pregelatinized Maize Starch)	7.332 mg.
		5	Colloidal silicon dioxide (Aerosil 200 Pharma)	1.32 mg.
		6	Magnesium Stearate	0.496 mg.
Doxepin HCL Capsules 25 mg (net content of active ingredients = 70.00 kgs)	1 Number	7	Doxepin Hydrochloride	28.384 mg.
		8	Microcrystalline cellulose (Avicel PH 302)	112.427 mg.
		9	Sodium Lauryl Sulfate (Kolliphor SLS Fine)	0.200 mg.
		10	Pregelatinized Starch (Starch 1500 Partially Pregelatinized Maize Starch	18.33 mg.
		11	Colloidal silicon dioxide (Aerosil 200 Pharma)	3.30 mg.

		12	Magnesium Stearate(Magnesium Stearate)	1.24 mg.
Doxepin HCL Capsules 50 mg (net content of active ingredients = 140.00 kgs)	1 Number	13	Doxepin Hydrochloride	56.766 mg.
		14	Microcrystalline cellulose (Avicel PH 302)	91.592 mg
		15	Sodium Lauryl Sulfate (Kolliphor SLS Fine)	1.313 mg.
		16	Pregelatinized Starch (Starch 1500 Partially Pregelatinized Maize Starch)	19.445 mg.
		17	Colloidal silicon dioxide (Aerosil 200 Pharma)	3.50 mg.
		18	Magnesium Stearate	1.312 mg.
Doxepin HCL Capsules 75 mg (net content of active ingredients = 90.00 kgs)	1 Number	19	Doxepin Hydrochloride	85.152 mg.
		20	Microcrystalline cellulose (Avicel PH 302)	137.388 mg.
		21	Sodium Lauryl Sulfate (Kolliphor SLS Fine)	1.969 mg.
		22	Pregelatinized Starch (Starch 1500 Partially Pregelatinized Maize Starch)	29.168 mg.
		23	Colloidal silicon dioxide (Aerosil 200 Pharma)	5.25 mg.
		24	Magnesium Stearate	1.969 mg.
Doxepin HCL Capsules 100	1 Number	25	Doxepin Hydrochloride	113.538 mg.

mg (net content of active ingredients = 120.00 kgs)		26	Microcrystalline cellulose (Avicel PH 302)	183.185 mg.
		27	Sodium Lauryl Sulfate (Kolliphor SLS Fine)	2.625 mg.
		28	Pregelatinized Starch (Starch 1500 Partially Pregelatinized Maize Starch)	38.890 mg.
		29	Colloidal silicon dioxide (Aerosil 200 Pharma)	7.00 mg.
		30	Magnesium Stearate	2.625 mg.

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

Case No.	12 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	RADHA KRISHNA IMPEX PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003806AM23
RA File Number	02AX04000380 AM23
Licence No and Date	0211003213/18/10/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it has been observed that export product applied by the firm pertains to Norms Committee-6, therefore, it has been decided that the application of the firm may be transferred to Norms Committee-6 for revision of ad-hoc norms.	

Case No.	13 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	YELLOWSTONE FINE CHEMICALS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025

and Date	
HQ File Number	HQRNORM APPLY 00008613AM24
RA File Number	03AX04005249 AM24
Licence No and Date	0311031269/16/02/2024
Norms Committee Decision: The Committee considered the case as per the agenda and observed that the reply to the Deficiency Letter has been submitted in the name of M/s Laxmi Organic Industries instead of M/s Yellowstone Fine Chemicals Private Limited. In view of this discrepancy, the Committee decided to call upon the firm to clarify whether a change of name has taken place from <i>M/s Yellowstone Fine Chemicals Private Limited</i> to <i>M/s Laxmi Organic Industries</i> and, if so, to furnish duly authenticated documentary evidence in support of the same.	

Case No.	14 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM REVIW00006320AM25
RA File Number	03AX04005442 AM24
Licence No and Date	0311031542/27/02/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has furnished the Weighted Average of Potency/Assay as sought by the Committee in its meeting held on 24.06.2025. However, the firm has not submitted the certified copy of the Customs test report or the Certificate of Analysis (CoA). Accordingly, the Committee decided to call upon the firm to furnish the aforesaid documents for further examination of the case..	

Case No.	15 / NC/3/MEET/Sep/202526/8
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM REVIW00004130AM25
RA File Number	03AX04000436 AM25
Licence No and Date	0311033409/29/04/2024

Norms Committee Decision:

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

Case No.	16 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00000484AM25
RA File Number	09AX04001160 AM24
Licence No and Date	0911007159/30/04/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	17 / NC/3/MEET/Sep/202526/8
Case Status	Case Rejected
Party Name	PRIGIV SPECIALTIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00000698AM25
RA File Number	03AX04000618 AM25
Licence No and Date	0311033818/14/05/2024
Norms Committee Decision:	
The firm was initially granted an Advance Authorisation for the export product “<i>LuzernyIsobutyrate</i>” under Para 4.07 of the Handbook of Procedures (HBP). However, as per Para 4.11(b) of the Foreign Trade Policy (FTP) 2023, products falling under the category of perfume or perfumery compounds are ineligible for authorisation under Para 4.07 and are mandatorily required to be processed under Para 4.06 of the HBP. It was observed that the firm obtained the authorisation by misdeclaring that its application was covered under the provisions of Para 4.07, and has not furnished any technical justification/information for the export product. Accordingly, the Committee found no merit in	

fixing the norms and decided to reject the application.

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

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

Case No.	18 / NC/3/MEET/Sep/202526/8
Case Status	Case Rejected
Party Name	PRIGIV SPECIALTIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00000797AM25
RA File Number	03AX04000605 AM25
Licence No and Date	0311033967/17/05/2024
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “<i>Luzerny Benzoate</i>” under Para 4.07 of the Handbook of Procedures (HBP). However, as per Para 4.11(b) of the Foreign Trade Policy (FTP) 2023, products falling under the category of perfume or perfumery compounds are ineligible for authorisation under Para 4.07 and are mandatorily required to be processed under Para 4.06 of the HBP. It was observed that the firm obtained the authorisation by misdeclaring that its application was covered under the provisions of Para 4.07, and has not furnished any technical justification/information for the export product. Accordingly, the Committee found no merit in fixing the norms and decided to reject the application. The RA shall ensure that the said authorisation is regularised by recovery of applicable Customs duty along with interest. Further, the RA should also submit a report on how this authorisation was issued under Para 4.07 of HBP, to the Chairperson of the Norms Committee and to PC-4 Section, DGFT Headquarters. The RA concerned may take further necessary action in line with the above decision of the Committee.	

Case No.	19 / NC/3/MEET/Sep/202526/8																
Case Status	Case Approved																
Party Name	MELOG SPECIALITY CHEMICALS PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025																
HQ File Number	HQRNORM APPLY 00000920AM25																
RA File Number	03AX04000829 AM25																
Licence No and Date	0311034133/27/05/2024																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202526/2 dated 08/05/2025 against advance authorization No.0311037677 dated 05/10/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">4,4-BIPHENOL</td><td rowspan="2">1 kg.</td><td>1</td><td>2,6-DI-TERT-BUTYL PHENOL</td><td>1.129 kg.</td></tr><tr><td>2</td><td>METHANOL</td><td>0.30 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	4,4-BIPHENOL	1 kg.	1	2,6-DI-TERT-BUTYL PHENOL	1.129 kg.	2	METHANOL	0.30 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
4,4-BIPHENOL	1 kg.	1	2,6-DI-TERT-BUTYL PHENOL	1.129 kg.													
		2	METHANOL	0.30 kg.													
RA concerned may take further necessary action as per above decision of NC																	

Case No.	20 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM REVIW00001502AM26
RA File Number	03AX04001280 AM25
Licence No and Date	0311034602/13/06/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Assurity Plus SPOT ON (For Small Cat) (Pack size 0.4ml x 6 pipettes),(Each ml contains: Imidacloprid EP 100mg andMoxidectin BP 10mg (Imidacloprid EP Net Weight = 240.00 gms& Moxidectin BP Net weight = 24.00 gms))	1000 Numbers	1	Imidacloprid EP	244.8 gm.
		25	Moxidectin BP	24.48 gm.
Assurity Plus SPOT ON (For Large Cat) (Pack size 0.8ml x 6 pipettes),(Each ml contains: Imidacloprid EP 100mg andMoxidectin BP 10 mg, (Imidacloprid EP Net Weight = 480.00 gms& Moxidectin BP Net weight = 48.00 gms))	1000 Numbers	2	Imidacloprid EP	489.6 gm.
		26	Moxidectin BP	48.96 gm.
Assurity Plus SPOT ON (For Small Dog) (Pack size 0.4ml x 6 Pipettes),(Each ml contains: Imidacloprid EP 100mg andMoxidectin BP 25 mg, (Imidacloprid EP Net Weight = 240.00 gms& Moxidectin BP Net weight = 60.00 gms))	1000 Numbers	3	Imidacloprid EP	244.8 gm.
		27	Moxidectin BP	61.2 gm.
Assurity Plus SPOT ON (For Medium Dog) (Pack size 1ml x 6 Pipettes),(Each ml contains: Imidacloprid EP 100mg andMoxidectin BP 25 mg, (Imidacloprid EP Net Weight = 600.00 gms& Moxidectin BP Net weight = 150.00gms))	1000 Numbers	4	Imidacloprid EP	612.0 gm.
		28	Moxidectin BP	153.0 gm.
Assurity Plus SPOT ON (For Large Dog) (Pack size 2.5ml x 6 Pipettes),(Each ml contains: Imidacloprid EP 100mg andMoxidectin BP 25 mg, (Imidacloprid EP Net Weight = 1500.00gms& Moxidectin BP Net weight = 375.00 gms))BP Net weight = 375.00 gms))	1000 Numbers	5	Imidacloprid EP	1530.0 gm.
		29	Moxidectin BP	382.5 gm.
Assurity Plus SPOT ON (For Extra Large Dog) (Pack size 4ml x 6 Pipettes),(Each	1500 Numbers	6	Imidacloprid EP	3672.0 gm.

ml contains: Imidacloprid EP 100mg and Moxidectin BP 25 mg, (Imidacloprid EP Net Weight = 3600.00 gms& Moxidectin BP Net weight = 900 gms))		30	Moxidectin BP	918.0 gm.
Nugard Spot On for Puppies and Dogs up to 4kg (Pack size 0.4ml x 1 Pipettes),(Each Litre contains: Imidacloprid EP 100gms and Moxidectin BP 25 gms, (Imidacloprid EP Net Weight = 40.00 gms& Moxidectin BP Net weight = 10.00 gms))	1000 Numbers	7	Imidacloprid EP	40.8 gm.
		31	Moxidectin BP	10.2 gm.
Nugard Spot On for Puppies and Dogs up to 4kg (Pack size 0.4ml x 3 Pipettes),(Each Litre contains: Imidacloprid EP 100Gms and Moxidectin BP 25 gms, (Imidacloprid EP Net Weight = 120.00 gms& Moxidectin BP Net weight = 30.00 gms))	1000 Numbers	8	Imidacloprid EP	122.4 gm.
		32	Moxidectin BP	30.6 gm.
Nugard Spot On for Puppies and Dogs up to 4kg (Pack size 0.4ml x 6 Pipettes),(Each Litre contains: Imidacloprid EP 100gms and Moxidectin BP 25 gms, (Imidacloprid EP Net Weight = 480.00 gms& Moxidectin BP Net weight = 120.00 gms))	2000 Numbers	9	Imidacloprid EP	489.6 gm.
		33	Moxidectin BP	122.4 gm.
Nugard Spot On for Dogs 4-10kg (Pack size 1ml x 1 Pipettes),(Each Litre contains: Imidacloprid EP 100 gms and Moxidectin BP 25 gms, (Imidacloprid EP Net Weight = 100.00 gms& Moxidectin BP Net weight = 25.00 gms))	1000 Numbers	10	Imidacloprid EP	102.0 gm.
		34	Moxidectin BP	25.5 gm.
Nugard Spot On for Dogs 4-10kg (Pack size 1ml x 3 Pipettes),(Each Litre contains: Imidacloprid EP 100 Gms and Moxidectin BP 25 gms, (Imidacloprid EP Net Weight = 600.00 gms& Moxidectin BP Net weight = 150.00 gms))	2000 Numbers	11	Imidacloprid EP	612.0 gm.
		35	Moxidectin BP	153.0 gm.

Nugard Spot On for Dogs 4-10 kg (Pack size 1ml x 6 Pipettes),(Each Litre contains: Imidacloprid EP 100 gmsandMoxidectin BP 25 gms, (Imidacloprid EP Net Weight = 2400.00 gms& Moxidectin BP Net weight = 600.00 gms))	4000 Numbers	12	Imidacloprid EP	2448.0 gm.
		36	Moxidectin BP	612.0 gm.
Nugard Spot On for Dogs 10- 25kg (Pack size 2.5ml x 1 Pipettes),(Each Litre contains: Imidacloprid EP 100 gmsandMoxidectin BP 25 gms,(Imidacloprid EP Net Weight = 250.00 gms& Moxidectin BP Net weight = 62.500 gms))	1000 Numbers	13	Imidacloprid EP	255.0 gm.
		37	Moxidectin BP	63.75 gm.
Nugard Spot On for Dogs 10- 25kg (Pack size 2.5ml x 3 Pipettes),(Each Litre contains: Imidacloprid EP 100 gmsandMoxidectin BP 25 gms, (Imidacloprid EP Net Weight = 1500.00 gms& Moxidectin BP Net weight = 375.00 gms))	2000 Numbers	14	Imidacloprid EP	1530.0 gm.
		38	Moxidectin BP	382.5 gm.
Nugard Spot On for Dogs 10- 25kg (Pack size 2.5ml x 6 Pipettes),(Each Litre contains: Imidacloprid EP 100 gmsand Moxidectin BP 25 gms, (Imidacloprid EP Net Weight = 3000.00 gms& Moxidectin BP Net weight = 750.00 gms))	2000 Numbers	15	Imidacloprid EP	3060.0 gm.
		39	Moxidectin BP	765.0 gm.
Nugard Spot On for Dogs over 25kg (Pack size 4ml x 1 Pipettes),(Each Litre contains: Imidacloprid EP 100 gmsandMoxidectin BP 25 gms, (Imidacloprid EP Net Weight = 400.00 gms& Moxidectin BP Net weight = 100.00 gms))	1000 Numbers	16	Imidacloprid EP	408.0 gm.
		40	Moxidectin BP	102.0 gm.
Nugard Spot On for Dogs over 25kg (Pack size 4ml x 3 Pipettes),(Each Litre contains: Imidacloprid EP 100 gmsandMoxidectin BP 25 gms, (Imidacloprid EP Net Weight = 2400.00 gms& Moxidectin BP Net	2000 Numbers	17	Imidacloprid EP	2448.0 gm.
		41	Moxidectin BP	612.0 gm.

weight = 600.00 gms))				
Nugard Spot On for Dogs over 25kg (Pack size 4ml x 6 Pipettes),(Each Litre contains: Imidacloprid EP 100 gmsandMoxidectin BP 25 gms, (Imidacloprid EP Net Weight = 7200.00 gms& Moxidectin BP Net weight = 1800.00 gms))	3000 Numbers	18	Imidacloprid EP	7344.0 gm.
		42	Moxidectin BP	1836.0 gm.
Nugard Spot On for kittens and cats up to 4 kg (Pack size 0.4ml x 1 Pipettes),(Each Litre contains: Imidacloprid EP 100Gms and Moxidectin BP 10 gms, (Imidacloprid EP Net Weight = 40.00 gms&Moxidectin BP Net weight = 4.00 gms))	1000 Numbers	19	Imidacloprid EP	40.8 gm.
		43	Moxidectin BP	4.08 gm.
Nugard Spot On for kittens and cats up to 4 kg (Pack size 0.4ml x 3 Pipettes),(Each Litre contains: Imidacloprid EP 100gmsand Moxidectin BP 10 gms, (Imidacloprid EP Net Weight = 300.00 gms& Moxidectin BP Net weight = 30.00 gms))	2500 Numbers	20	Imidacloprid EP	306.0 gm.
		44	Moxidectin BP	30.6 gm.
Nugard Spot On for kittens and cats up to 4 kg (Pack size 0.4ml x 6 Pipettes),(Each Litre contains: Imidacloprid EP 100gms and Moxidectin BP 10 gms,(Imidacloprid EP Net Weight = 960.00 gms& Moxidectin BP Net weight = 96.00 gms))	4000 Numbers	21	Imidacloprid EP	979.2 gm.
		45	Moxidectin BP	97.92 gm.
Nugrad Spot On Cats over 4 kg (Pack size 0.8ml x 1 Pipettes),(Each Litre contains: Imidacloprid EP 100 gmsandMoxidectin BP 10 gms, (Imidacloprid EP Net Weight = 80.00 gms& Moxidectin BP Net weight = 8.00 gms))	1000 Numbers	22	Imidacloprid EP	81.6 gm.
		46	Moxidectin BP	8.16 gm.
Nugrad Spot On Cats over 4 kg (Pack size 0.8ml x 3 Pipettes),(Each Litre contains: Imidacloprid EP 100 gmsandMoxidectin BP 10 gms, (Imidacloprid EP Net Weight	2500 Numbers	23	Imidacloprid EP	612.0 gm.
		47	Moxidectin BP	61.2 gm.

= 600.00 gms& Moxidectin BP Net weight = 60.00 gms))				
Nugrad Spot On Cats over 4 kg (Pack size 0.8ml x 6 Pipettes),(Each Litre contains: Imidacloprid EP 100 gmsandMoxidectin BP 10 gms, (Imidacloprid EP Net Weight = 4800.00 gms& Moxidectin BP Net weight = 480.00 gms))	10000 Numbers	24	Imidacloprid EP	4896.0 gm.
		48	Moxidectin BP	489.6 gm.

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

Case No.	21 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00001820AM25
RA File Number	52AX04000089 AM25
Licence No and Date	5211008812/08/07/2024
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 documents from the firm.	

Case No.	22 / NC/3/MEET/Sep/202526/8
Case Status	Case Rejected
Party Name	GLAND PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00002566AM25
RA File Number	09AX04000345 AM25
Licence No and Date	0911007758/19/08/2024
Norms Committee Decision:	

The Committee considered the case as per agenda and it has been observed that the firm vide their e-mail dated 16.09.2025 has informed that they have not utilized the Advance Authorisation and the same has been cancelled by concerned RA. Therefore, it was decided to close the application of the firm.

Case No.	23 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00002569AM25
RA File Number	09AX04000367 AM25
Licence No and Date	0911007762/19/08/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Phentermine and Topiramate Extended Release Capsules 3.75/23mg US Pack Size:30s (Consisting of Phentermine 10.13Kgs)	2700000 Numbers	1	Phentermine Hydrochloride USP	12.58 kg.
Phentermine and Topiramate Extended Release Capsules 7.50/46mg US Pack Size:30s (Consisting of Phentermine 40.50Kgs)	5400000 Numbers	2	Phentermine Hydrochloride USP	50.38 kg.
Phentermine and Topiramate Extended Release Capsules 11.25/69mg US Pack Size:30s (Consisting of Phentermine 29.70Kgs)	2640000 Numbers	3	Phentermine Hydrochloride USP	36.96 kg.
Phentermine and Topiramate Extended Release Capsules 15/92mg US Pack Size:30s (Consisting of Phentermine 39.60Kgs)	2640000 Numbers	4	Phentermine Hydrochloride USP	49.26 kg.

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

Case No.	24 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	MELOG SPECIALITY CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00002583AM25
RA File Number	03AX04002187 AM25
Licence No and Date	0311036462/20/08/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202526/2 dated 08/05/2025 against advance authorization No.0311037677 dated 05/10/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4,4-BIPHENOL	1 kg.	1	2,6-DI-TERT-BUTYL PHENOL	1.129 kg.
		2	METHANOL	0.30 kg.

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

Case No.	25 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025

HQ File Number	HQRNORM APPLY 00002619AM25													
RA File Number	31AX04000169 AM25													
Licence No and Date	3111003807/21/08/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>DNOVO CP388 (Tetra Methyl Bisphenol-A)</td><td>1 kg.</td><td>1</td><td>2,6 xyleneol</td><td>1.19 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DNOVO CP388 (Tetra Methyl Bisphenol-A)	1 kg.	1	2,6 xyleneol	1.19 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
DNOVO CP388 (Tetra Methyl Bisphenol-A)	1 kg.	1	2,6 xyleneol	1.19 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	26 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00002727AM25
RA File Number	03AX04002597 AM25
Licence No and Date	0311036698/28/08/2024
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
Copy of Master-Batch Formula for each export item showing net content of import item in the export.	

Case No.	27 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	CLARIANT INDIA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00002789AM25			

RA File Number	03AX04002663 AM25			
Licence No and Date	0311036805/02/09/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No.0311034385 dated 05/06/2024, 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.
Piroctone Olamine or Vipirox (OctopiroxPlus)	1 kg	1	Dimethyl Acrylic Acid Ester	0.770 kg
		2	Hydroxyl ammonium sulfate	1.628 kg
		3	Isononyl Acid Chloride	1.515 kg
		4	Mono Ethanol Amine	0.372 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	28 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00002874AM25
RA File Number	09AX04000408 AM25
Licence No and Date	0911007869/05/09/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jul/202526/6dated 31/07/2025against advance authorization No.0911008698dated24/12/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Atinvcitinib((or) 1-[(3R,4S)-4-Cyanotetrahydropyran-3-yl]-3-[(2-fluoro-6-methoxy-4-pyridyl) amino]pyrazole-4-carboxamide (L-005251026-Form-I))	1 kg	1	2-Fluoro-6-methoxy pyridine (FMP)	1.975 kg
		2	4,5-bis(Diphenylphosphino)-9,9-dimethylxanthane (Xantphos)	0.125 kg

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

Case No.	29 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003039AM25
RA File Number	09AX04000248 AM25
Licence No and Date	0911007949/13/09/2024
Norms Committee Decision:	
The firm was called for Personal Hearing on 17/09/2025 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one last opportunity to the firm for Personal Hearing with relevant documents/information.	

Case No.	30 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003481AM25
RA File Number	52AX04000198 AM25
Licence No and Date	5211010153/04/10/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export	

product/import product in meeting No.NC/3/MEET/May/202425/4dated 06/06/2024 against advance authorization No. 5211007605 dated 07/03/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRIAMICINOLONE IP/EP/BP/USP	1 kg.	1	3,20-DIOXOPREGNA-1,4,9(11),16 - TETRAEN - 21-YLACETATE (3 TR)	1.00 kg.

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

Case No.	31 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	SAGA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003526AM25
RA File Number	08AX04001122 AM25
Licence No and Date	0811012864/08/10/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Diosmin + Hesperidin 1000 mg Suspension (75.52 KGS)	75517 Numbers	1	Diosmin and Hesperidin 9:1(DIOSMIN + HESPERIDIN 9:1 (ASSAY NMT 93% AND WATER CONTENT NLT 2.9%))	79.293 kg.

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

Case No.	32 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	PI INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003572AM25
RA File Number	13AX04000225 AM25
Licence No and Date	1311003391/09/10/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Percentage yield on molar basis for each step of manufacturing process with justification.	

Case No.	33 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003598AM25
RA File Number	09AX04000471 AM25
Licence No and Date	0911008128/10/10/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant information / documents from the firm.	

Case No.	34 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003600AM25
RA File Number	09AX04000467 AM25
Licence No and Date	0911008130/10/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant information / documents from the firm.

Case No.	35 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003633AM25
RA File Number	03AX04003448 AM25
Licence No and Date	0311037925/15/10/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Complete chemistry, chemical reaction, Stoichiometric balance on molar basis with molecular weight and percentage yield for each step of reaction.	

Case No.	36 / NC/3/MEET/Sep/202526/8
Case Status	Case Rejected
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003646AM25
RA File Number	34AX04000564 AM25
Licence No and Date	3411005540/15/10/2024
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “Anisole” 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.	37 / NC/3/MEET/Sep/202526/8
Case Status	Case Rejected
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003672AM25
RA File Number	34AX04000597 AM25
Licence No and Date	3411005544/16/10/2024

Norms Committee Decision:

The firm was initially granted an Advance Authorisation for the export product “*Anisole*” 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.	38 / NC/3/MEET/Sep/202526/8
Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003724AM25
RA File Number	03AX04003565 AM25
Licence No and Date	0311038045/18/10/2024

Norms Committee Decision:

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

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

The RA shall ensure that the said authorisation is 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.	39 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	MEDICARE HYGIENE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025

HQ File Number	HQRNORM APPLY 00003843AM25
RA File Number	08AX04001190 AM25
Licence No and Date	0811013002/24/10/2024
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed that export product applied by the firm pertains to Norms Committee-5, therefore, it has been decided that the application of the firm may be transferred to Norms Committee-5 for the fixation of ad-hoc norms.	

Case No.	40 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	PRACHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003845AM25
RA File Number	08AX04001204 AM25
Licence No and Date	0811013007/24/10/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with following information / documents from the firm: 1. Copy of Drug Manufacturing Licence (DML). 2. Whether export in BP/USP/EP grade, if so, get the grade endorsed in the Advance Authorisation from concerned RA.	

Case No.	41 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003846AM25
RA File Number	52AX04000212 AM25
Licence No and Date	5211010462/24/10/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-{1-[(2S)-2-Aminopropyl]-1-H-Pyrazole-3-yl}-2- Chlorobenzonitrile)	1 kg.	1	2-chloro-4-(1H-pyrazol-3-yl) benzonitrile	0.963 kg.
		2	Tert-Butyl ((1S)-2-hydroxy-1-methylethyl) carbamate	0.826 kg.
		3	Diisopropyl azodicarboxylate	1.034 kg.
		4	Triphenylphosphine	1.237 kg.

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

Case No.	42 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	LAZERHEAD LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003851AM25
RA File Number	09AX04000499 AM25
Licence No and Date	0911008210/24/10/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ovaplant 250 mcg ((Salmon Gonadotropin Releasing Hormone Analogue Implant))	1 Number	1	Salmon Gonadorelin	255.00 mcg.
Ovaplant 150 mcg ((Salmon	1 Number	2	Salmon Gonadorelin	153.00 mcg.

Gonadotropin Releasing Hormone Analogue Implant))				
Ovaplant 75 mcg ((Salmon Gonadotropin Releasing Hormone Analogue Implant))	1 Number	3	Salmon Gonadorelin	76.50 mcg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	43 / NC/3/MEET/Sep/202526/8																							
Case Status	Case Approved																							
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED																							
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025																							
HQ File Number	HQRNORM APPLY 00003868AM25																							
RA File Number	08AX04001241 AM25																							
Licence No and Date	0811013030/25/10/2024																							
Norms Committee Decision:																								
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																								
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Nicardipine Hydrochloride Injection USP, 2.5 mg/mL (10 mL)</td><td>1 Number Vial</td><td>1</td><td>Nicardipine Hydrochloride USP</td><td>26.25 mg/10 ml. Vial</td></tr><tr><td>Nicardipine Hydrochloride in 0.9 % Sodium Chloride Injection, 0.2 mg/mL (40 mg/200 mL)</td><td>1 Number Vial</td><td>2</td><td>Nicardipine Hydrochloride USP</td><td>42.00 mg/200 ml Vial</td></tr><tr><td>Nicardipine Hydrochloride in 0.9 % Sodium Chloride Injection, 0.1 mg/mL (20 mg/200 mL)</td><td>1 Number Vial</td><td>3</td><td>Nicardipine Hydrochloride USP</td><td>21.00 mg/200 ml.Vial</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Nicardipine Hydrochloride Injection USP, 2.5 mg/mL (10 mL)	1 Number Vial	1	Nicardipine Hydrochloride USP	26.25 mg/10 ml. Vial	Nicardipine Hydrochloride in 0.9 % Sodium Chloride Injection, 0.2 mg/mL (40 mg/200 mL)	1 Number Vial	2	Nicardipine Hydrochloride USP	42.00 mg/200 ml Vial	Nicardipine Hydrochloride in 0.9 % Sodium Chloride Injection, 0.1 mg/mL (20 mg/200 mL)	1 Number Vial	3	Nicardipine Hydrochloride USP	21.00 mg/200 ml.Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																				
Nicardipine Hydrochloride Injection USP, 2.5 mg/mL (10 mL)	1 Number Vial	1	Nicardipine Hydrochloride USP	26.25 mg/10 ml. Vial																				
Nicardipine Hydrochloride in 0.9 % Sodium Chloride Injection, 0.2 mg/mL (40 mg/200 mL)	1 Number Vial	2	Nicardipine Hydrochloride USP	42.00 mg/200 ml Vial																				
Nicardipine Hydrochloride in 0.9 % Sodium Chloride Injection, 0.1 mg/mL (20 mg/200 mL)	1 Number Vial	3	Nicardipine Hydrochloride USP	21.00 mg/200 ml.Vial																				
RA concerned may take further necessary action as per above decision of NC.																								

Case No.	44 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	DR.REDDY'S LABORATORIES LTD			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00003943AM25			
RA File Number	09AX04000560 AM25			
Licence No and Date	0911008287/29/10/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Apr/202526/1dated 25/04/2025 against advance authorization No. 0911005577 dated 04/08/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Diluted Everolimus 5%	1 kg.	1	Everolimus (Spec-1)	0.051 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	45 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	PARADISE HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00003965AM25
RA File Number	34AX04000658 AM25
Licence No and Date	3411005628/30/10/2024
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	

Percentage yield on molar basis for each step of manufacturing process supported by technical literature.

Case No.	46 / NC/3/MEET/Sep/202526/8													
Case Status	Case Approved													
Party Name	OC SPECIALITIES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025													
HQ File Number	HQRNORM APPLY 00005355AM25													
RA File Number	03AX04005058 AM25													
Licence No and Date	0311040130/02/01/2025													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>M-DEA</td><td>1 kg.</td><td>1</td><td>2,6-DIETHYL ANILINE (DEA)</td><td>1.20 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	M-DEA	1 kg.	1	2,6-DIETHYL ANILINE (DEA)	1.20 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
M-DEA	1 kg.	1	2,6-DIETHYL ANILINE (DEA)	1.20 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	47 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005684AM25
RA File Number	08AX04001751 AM25
Licence No and Date	0811013820/16/01/2025
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sevelamer Carbonate For Oral Suspension 2.4 g (Sevelamer Carbonate 2.4 g Powder For Oral Suspension Sachets/Packets)(Each Packets/ Sachets Contains : Sevelamer Carbonate For Oral Suspension 2.4 gram Net Content Of Sevelamer Carbonate Should Not Be Less Than 40.800 kg In Export Item)	17000 Numbers	1	Sevelamer Carbonate	42.84 kg.

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

Case No.	48 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	ABHILASH LIFE SCIENCES LLP
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005689AM25
RA File Number	32AX04000688 AM25
Licence No and Date	3211008262/16/01/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Valsartan 40 mg Capsules	1 Number	1	Valsartan	40.8 mg/Capsule

Valsartan 80 mg Capsules	1 Number	2	Valsartan	81.6 mg/Capsule
Valsartan 160 mg Capsules	1 Number	3	Valsartan	163.2 mg/Capsule

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

Case No.	49 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	S KANT HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005704AM25
RA File Number	03AX04005307 AM25
Licence No and Date	0311040532/17/01/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Aug/202526/7dated 22/08/2025 against advance authorization No. 0311029247dated 11/12/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

(A)

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Artemether 20 mg & Lumefantrine 120 mg Tablets	1 Number Tablet	1	Artemether	20.4 mg.
		2	Lumefantrine	122.4 mg.
Artemether 20 mg & Lumefantrine 120 mg Dispersible Tablets	1 Number Tablet	1	Artemether	20.4 mg.
		2	Lumefantrine	122.4 mg.
Artemether 40 mg & Lumefantrine 240 mg	1 Number Tablet	1	Artemether	40.8 mg.
		2	Lumefantrine	244.8 mg.

Artemether 80 mg & Lumefantrine 480 mg Tablets	1 Number Tablet	1	Artemether	81.6 mg.
		2	Lumefantrine	489.6 mg.

(B)

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Artemether	1 kg.	1	Artemisinin	1.04 kg.
		2	Sodium Borohydride	0.188 kg.
		3	Trimethyl Ortho Acetate 99% Min	0.50 kg.

(C)

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Lumefantrine	1 kg.	1	2, 7 Dichloro A Dibutylamino Methyl 9 Hfluorene-4-Methanol DBA 99% Min	0.86896 kg.
		2	4 - Chlorobenzaldehyde	0.3476 kg.

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

Case No.	50 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	UMALAXMI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005705AM25
RA File Number	13AX04000328 AM25
Licence No and Date	1311003622/17/01/2025
Norms Committee Decision:	

The Committee considered the case as per agenda and it has been observed that export product applied by the firm pertains to Norms Committee-6, therefore, it has been decided that the application of the firm may be transferred to Norms Committee-6 for the fixation of ad-hoc norms.

Case No.	51 / NC/3/MEET/Sep/202526/8													
Case Status	Case Approved													
Party Name	DCM NOUVELLE SPECIALTY CHEMICALS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025													
HQ File Number	HQRNORM APPLY 00005711AM25													
RA File Number	05AX04003667 AM25													
Licence No and Date	0511030378/17/01/2025													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Benzylamine</td><td>1 kg.</td><td>1</td><td>Benzonitrile</td><td>1.07 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Benzylamine	1 kg.	1	Benzonitrile	1.07 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Benzylamine	1 kg.	1	Benzonitrile	1.07 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	52 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	CLARIANT INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005757AM25
RA File Number	03AX04005387 AM25
Licence No and Date	0311040605/21/01/2025
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.0311034385 dated 05/06/2024, 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.
Piroctone Olamine or Vipirox (OctopiroxPlus)	1 kg	1	Dimethyl Acrylic Acid Ester	0.770 kg
		2	Hydroxyl ammonium sulfate	1.628 kg
		3	Isononyl Acid Chloride	1.515 kg
		4	Mono Ethanol Amine	0.372 kg

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

Case No.	53 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	KALPSUTRA GUJARAT
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005770AM25
RA File Number	34AX04000913 AM25
Licence No and Date	3411005984/21/01/2025

Norms Committee Decision:

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

1. End use of export product.
2. Certificate of Analysis (CoA) of export item indicating percentage purity.
3. Wastages at each stage of manufacturing.
4. Justification of low yield.

Commercial value of low and high boiler.

Case No.	54 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005775AM25
RA File Number	03AX04005395 AM25
Licence No and Date	0311040632/21/01/2025
Norms Committee Decision:	
The committee considered the case as per agenda and it was decided to fix ad-hoc norms as per SION A-412.	

Case No.	55 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005789AM25
RA File Number	09AX04000881 AM25
Licence No and Date	0911008880/22/01/2025
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant information / documents from the firm.	

Case No.	56 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	ALCHYMARS ICM SM PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025

and Date	
HQ File Number	HQRNORM APPLY 00005800AM25
RA File Number	04AX04001008 AM25
Licence No and Date	0411008933/22/01/2025
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with following information / documents from the firm: 1. Improvement in the conversioin yield in the last 10 years with batch-log sheet for recent 10 batches. 2. Past production/consumption data for the year 2022-23, 2023-24 and 2024-25 duly certified by CA. 3. Batch log sheet for import made in recent three licences.	

Case No.	57 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	SPAR PHARMA LLP			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00005802AM25			
RA File Number	09AX04000901 AM25			
Licence No and Date	0911008883/22/01/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-Fluoro-alpha-[2-methyl-1-oxopropyl]-gamma-oxo-N-beta-diphenyl benzene butanamide(SOLID)	1 kg.	1	Aniline Oil (Liquid)	0.47 kg.
		2	Fluorobenzene (Liquid)	0.52 kg.
		3	Acetone (Liquid)	0.50 kg.
		4	Methyl Aceto Acetate (Liquid)	1.06 kg.

		5	Iso Butyryl Chloride (Liquid)	0.97 kg.
		6	Iso Propyl Alcohol (IPA) (Liquid)	Not showing in the past consumption data
RA concerned may take further necessary action as per above decision of NC.				

Case No.	58 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005808AM25
RA File Number	09AX04000882 AM25
Licence No and Date	0911008886/22/01/2025
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant information / documents from the firm:	

Case No.	59 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005811AM25
RA File Number	08AX04001768 AM25
Licence No and Date	0811013886/23/01/2025
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/202526/3 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Magnesium Sulfate In Water for Injection (0.325 mEq Mg ⁺⁺ /mL) 40 mg/mL 2g Total	1 Number	1	Magnesium Sulfate Heptahydrate PhEur, USP, Injectable grade	2.00 gm
Magnesium Sulfate In Water for Injection (0.325 mEq Mg ⁺⁺ /mL) 40 mg/mL 4g Total	1 Number	2	Magnesium Sulfate Heptahydrate PhEur, USP, Injectable grade	4.00 gm.

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

Case No.	60 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	BIOMATRIX HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005847AM25
RA File Number	08AX04001762 AM25
Licence No and Date	0811013905/24/01/2025
Norms Committee Decision:	
The Committee has decided to defer the case for next meeting.	

Case No.	61 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	FLAGSHIP BIOTECH INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005855AM25

RA File Number	03AX04005459 AM25			
Licence No and Date	0311040715/24/01/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
OKSIMAKS SPRAY((Oxytetracycline Hydrochloride 25mg,Florfenicol 25 mg, Gentian Violet 5mg Spray Solution,),1 x 200ml)	1 Number Bottle	1	Florfenicol	5.10 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	62 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	STERILE INDIA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00005860AM25			
RA File Number	05AX04003696 AM25			
Licence No and Date	0511030545/24/01/2025			
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/202223/12 dated 18/11/2022 against advance authorization No.0511011543 dated 31/03/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
VANCOMYCIN HYDROCHLORIDE (STERILE)	1 kg.	1	Vancomycin	1.01 kg.

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

Case No.	63 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005910AM25
RA File Number	03AX04005472 AM25
Licence No and Date	0311040840/29/01/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ciclesonide inhalation aerosol 100 mcg 120MD / Ciclesonide inhalation aerosol 100 mcg/actuation (ex-valve)((Net Wt. of Ciclesonide Ph. Eur. Is Qty. 840 Grams))	70000 Numbers	1	Ciclesonide Ph. Eur.	856.8 gm.
Ciclesonide inhalation aerosol 200 mcg 120MD / Ciclesonide inhalation aerosol 200 mcg/actuation (ex-valve)((Net Wt. of Ciclesonide Ph. Eur. Is Qty. 2880 Grams))	120000 Numbers	2	Ciclesonide Ph. Eur.	2937.6 gm.

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

Case No.	64 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005920AM25
RA File Number	03AX04005299 AM25
Licence No and Date	0311040876/29/01/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Copy of Master-Batch Formula for each export in showing net content of each ingredient in the export.	

Case No.	65 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	STERILE INDIA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00005922AM25			
RA File Number	05AX04003756 AM25			
Licence No and Date	0511030623/29/01/2025			
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.0511027808 dated 18/03/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ceftriaxone Sodium Sterile	1 kg.	1	Ceftriaxone Sodium (Non Sterile)	1.04 kg.

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

Case No.	66 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005925AM25
RA File Number	31AX04000397 AM25
Licence No and Date	3111004376/29/01/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202324/25** dated 11/03/2024 against advance authorization **No. 0311028861** dated 23/11/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sodium Lactate (Hartmann's) 1000 ml	1 Number	1	Sodium Lactate (PurasalSP/F 50)(EP)	Net content in export + 2% wastage.
		2	Potassium Chloride EP	Net content in export + 2% wastage.
		3	Calcium Chloride EP	Net content in export + 2% wastage.
		4	Sodium Chloride (SANAL) (EP)	Net content in export + 2% wastage.
		5	SF9-11 195/140 (PLASTIC FILM	Net content in

			(NON-PVC) FOR PRIMARY PACKING) (0369631)	export + 1% wastage.
		6	OFR2-11 120/524 PHTALATFREE (PLASTIC FILM (NON-PVC) FOR SECONDARY PACKING (0369681)	Net content in export + 1% wastage.
		7	UFR2-11 150/524 PHTALATFREE (PLASTIC FILM (NON-PVC) FOR SECONDARY PACKING (0369661)	Net content in export + 1% wastage.
		8	SSC Infusion Port (0434181)	Net content in export + 1% wastage.
		9	SSC Injection Port (Art. 0434371)	Net content in export + 1% wastage.
		10	BOP Infusion Port (Art.No 0434171)	Net content in export + 1% wastage.
		11	BOP Injection Port (Art. 0434481)	Net content in export + 1% wastage.
		12	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	67 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred

Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005926AM25
RA File Number	31AX04000396 AM25
Licence No and Date	3111004377/29/01/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	68 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	VARTIKA CHEMICALS AND PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005931AM25
RA File Number	13AX04000347 AM25
Licence No and Date	1311003649/30/01/2025
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Composition of export item showing percentage content of API in the export supported by Certificate of Analysis (CoA) of export item and Master-Batch Formula.	

Case No.	69 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005934AM25
RA File Number	03AX04005533 AM25
Licence No and Date	0311040887/30/01/2025
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the	

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

1. Certificate of Analysis (CoA) of import item from Foreign Supplier.
2. Weighted Average of Potency/Assay of the API imported.

Case No.	70 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005959AM25
RA File Number	03AX04005511 AM25
Licence No and Date	0311040909/30/01/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.**NC/3/MEET/Jun/202025/5 dated 30/06/2025 against advance authorization **No.** 0311039799 dated 20/12/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

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

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

Case No.	71 / NC/3/MEET/Sep/202526/8										
Case Status	Case Approved										
Party Name	MICRO LABS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025										
HQ File Number	HQRNORM APPLY 00005962AM25										
RA File Number	07AX04001802 AM25										
Licence No and Date	0711013517/30/01/2025										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jun/202425/19 dated 27/03/2025 against advance authorization No. 0711012089 dated 14/08/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Ramelteon 8 mg Tablets</td><td>1 Number Tablet</td><td>1</td><td>Ramelteon</td><td>8.16 mg/Tablet</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ramelteon 8 mg Tablets	1 Number Tablet	1	Ramelteon	8.16 mg/Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Ramelteon 8 mg Tablets	1 Number Tablet	1	Ramelteon	8.16 mg/Tablet							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	72 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	MEDREICH LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00005963AM25			
RA File Number	07AX04001809 AM25			
Licence No and Date	0711013518/30/01/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jul/202526/6 dated 31/07/2025 against advance authorization No. 0711013347 dated 15/01/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Clindamycin Hydrochloride 300 mg Capsules [1628.900 KG] [Each Capsule contains Clindamycin Hydrochloride 325.78 mg equivalent to Clindamycin 300 mg])	1 Number	1	Clindamycin Hydrochloride Ph.Eur	332.29 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	73 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	PANACEA BIOTEC PHARMA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00005970AM25			
RA File Number	05AX04003703 AM25			
Licence No and Date	0511030649/31/01/2025			

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Paclitaxel (Protein-Bound Particles for Injectable Suspension 100 mg) Pacliall	19853 Vials	1	Albumin Human USP (25%) Solution	72.9 Liter

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

Case No.	74 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00005984AM25
RA File Number	03AX04005605 AM25
Licence No and Date	0311040984/01/02/2025

Norms Committee Decision:

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

Composition of export items do not match with composition given in Drug Manufacturing Licence (DML). Please justify the reason and get the licence amended in line with DML.

Case No.	75 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025

and Date																	
HQ File Number	HQRNORM APPLY 00005993AM25																
RA File Number	31AX04000415 AM25																
Licence No and Date	3111004396/03/02/2025																
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table 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="3">DNOVO BP838 (Tetra Methyl Bisphenol-A)</td> <td rowspan="3">1 kg.</td> <td>1</td> <td>2,6 xyleneol</td> <td>1.19 kg.</td> </tr> <tr> <td>2</td> <td>Toluene</td> <td>0.283 kg.</td> </tr> <tr> <td>3</td> <td>Acetone</td> <td>0.231 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.	DNOVO BP838 (Tetra Methyl Bisphenol-A)	1 kg.	1	2,6 xyleneol	1.19 kg.	2	Toluene	0.283 kg.	3	Acetone	0.231 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
DNOVO BP838 (Tetra Methyl Bisphenol-A)	1 kg.	1	2,6 xyleneol	1.19 kg.													
		2	Toluene	0.283 kg.													
		3	Acetone	0.231 kg.													

Case No.	76 / NC/3/MEET/Sep/202526/8								
Case Status	Case Approved								
Party Name	AARTI DRUGS LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025								
HQ File Number	HQRNORM APPLY 00006000AM25								
RA File Number	03AX04005208 AM25								
Licence No and Date	0311041035/04/02/2025								
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					

Levofloxacin USP	1 kg.	1	Levofloxacin Q-Acid	0.856 kg.
		2	N, Methyl Piperazine	0.432 kg.
		3	Methanol	0.366 kg.
		4	Caustic Soda Flakes	0.190 kg.

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

Case No.	77 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006001AM25
RA File Number	03AX04005544 AM25
Licence No and Date	0311041038/04/02/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,15 diethyl 2,2,14,14-tetramethyl-8-oxopentadecanedioate	1 kg.	1	Tetrahydrofuran	1.125 kg.
		2	n-Heptane	1.787 kg.
		3	Ethyl Isobutyrate	0.686 kg.
		4	1 Bromo-5-chloropentane	1.10 kg.

		5	N, N Dimethylacetamide	1.675 kg.
		6	Sodium t-pentoxide	0.567 kg.
		7	Tosmic	0.512 kg.
		8	N-butyl lithium (25% in N-Heptane)	1.826 kg.

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

Case No.	78 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006003AM25
RA File Number	07AX04001828 AM25
Licence No and Date	0711013540/04/02/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Lisinopril 5mg + Amlodipine 5 mgTablets(21.00Kgs)	1 Number Tablet	1	Lisinopril Dihydrate Ph.Eur	5.10 mg.
		2	Amlodipine Besilate BP	5.10 mg.
Lisinopril 10 mg + Amlodipine 5mg Tablets(40.50kgs)	1 Number	3	Lisinopril Dihydrate Ph.Eur	10.2 mg.

	Tablet	4	Amlodipine Besilate BP	5.10 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	79 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00006004AM25			
RA File Number	07AX04001834 AM25			
Licence No and Date	0711013545/04/02/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxycycline 100 mg Dispersible Tablets (Eq. To Anhydrous Doxycycline 100 mg)	1 Number Tablet	1	Doxycycline Monohydrate USP/BP	106.13 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	80 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00006007AM25			
RA File Number	07AX04001830 AM25			

Licence No and Date	0711013550/04/02/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tranexamic Acid Injection Solution 1000 mg / 10ml (Net Contents 22.50kg)	22500 Numbers	1	Tranexamic Acid BP/EP/IP/USP	24.75 kg.

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

Case No.	81 / NC/3/MEET/Sep/202526/8																		
Case Status	Case Approved																		
Party Name	LEGENCY REMEDIES PRIVATE LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025																		
HQ File Number	HQRNORM APPLY 00006011AM25																		
RA File Number	30AX04000637 AM25																		
Licence No and Date	3011006460/04/02/2025																		
Norms Committee Decision:																			
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																			
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Sterilised Water for Injections BP 10 ml</td><td>1 Number</td><td>1</td><td>Low Density Polyethylene Medical Grade :BB 120 /150</td><td>1.03 kg/kg content in the export product.</td></tr><tr><td>Dextrose Injection USP 40%</td><td>1 Number</td><td>2</td><td>Low Density</td><td>1.03 kg/kg content in the</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sterilised Water for Injections BP 10 ml	1 Number	1	Low Density Polyethylene Medical Grade :BB 120 /150	1.03 kg/kg content in the export product.	Dextrose Injection USP 40%	1 Number	2	Low Density	1.03 kg/kg content in the
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Sterilised Water for Injections BP 10 ml	1 Number	1	Low Density Polyethylene Medical Grade :BB 120 /150	1.03 kg/kg content in the export product.															
Dextrose Injection USP 40%	1 Number	2	Low Density	1.03 kg/kg content in the															

W/v 20 ml			Polyethylene Medical Grade :BB 120 /150	export product.
Salbutamol 2.5 mg/2.5ml	1 Number	3	Low Density Polyethylene Medical Grade :BB 120 /150	1.03 kg/kg content in the export product. .

Note: (i) The firm will declare net content of import item in each export in the Shipping Bill.

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

Case No.	82 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006027AM25
RA File Number	03AX04005587 AM25
Licence No and Date	0311041065/05/02/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Copy of Master-Batch Formula for each export item.	

Case No.	83 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	PUNJAB CHEMICALS AND CROP PROTECTION LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006042AM25
RA File Number	03AX04005681 AM25
Licence No and	0311041097/06/02/2025

Date	
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Complete chemistry, chemical reaction, Stoichiometric balance on molar basis with molecular weight and percentage yield for each step of reaction.	

Case No.	84 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	PLASTIBLENDS INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006045AM25
RA File Number	03AX04005636 AM25
Licence No and Date	0311041109/06/02/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Additive Masterbatch (Net Content:1)Relevant polymer such as Hydrocarbon Resin: 1,48,500 kgs. 2) Additive namely Antioxidant: 297.000 kgs 3) Relevant polymers such as BOPP:1,48,203.00 KGS)	297000 kg.	1	Relevant polymer such as Hydrocarb on Resin	152955 kg.
		2	Additive namely Antioxidant	305.91 kg.
		3	Relevant polymers such as BOPP	152649 kg.

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

Case No.	85 / NC/3/MEET/Sep/202526/8																		
Case Status	Case Approved																		
Party Name	CUCKOS PHARMACEUTICAL PRIVATE LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025																		
HQ File Number	HQRNORM APPLY 00006049AM25																		
RA File Number	05AX04003457 AM25																		
Licence No and Date	0511030734/06/02/2025																		
Norms Committee Decision:																			
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																			
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Oclacitnib Maleate Tablets 5.4 mg</td><td>1 Number</td><td>1</td><td>Oclacitinib Maleate</td><td>7.588 mg.</td></tr><tr><td>Oclacitnib Maleate Tablets 16 mg</td><td>1 Number</td><td>2</td><td>Oclacitinib Maleate</td><td>22.48 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Oclacitnib Maleate Tablets 5.4 mg	1 Number	1	Oclacitinib Maleate	7.588 mg.	Oclacitnib Maleate Tablets 16 mg	1 Number	2	Oclacitinib Maleate	22.48 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Oclacitnib Maleate Tablets 5.4 mg	1 Number	1	Oclacitinib Maleate	7.588 mg.															
Oclacitnib Maleate Tablets 16 mg	1 Number	2	Oclacitinib Maleate	22.48 mg.															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	86 / NC/3/MEET/Sep/202526/8
Case Status	Case Rejected
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006056AM25
RA File Number	34AX04000966 AM25
Licence No and Date	3411006053/06/02/2025
Norms Committee Decision:	
The firm was initially granted an Advance Authorisation for the export product “Allyl Caproate” 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.	87 / NC/3/MEET/Sep/202526/8
Case Status	Case Rejected
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006069AM25
RA File Number	34AX04000969 AM25
Licence No and Date	3411006055/07/02/2025

Norms Committee Decision:

The firm was initially granted an Advance Authorisation for the export product “Ozonal” 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.	88 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006079AM25
RA File Number	03AX04005625 AM25
Licence No and Date	0311041044/07/02/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MOXILEB -CV -375 TABLET USP. (AMOXICILLIN & CLAVULANATE POTASSIUM TABLETS USP 375MG) (((EACH TABLET CONTAINING AMOXICILLIN TRIHYDRATE EQUIVALENT TO 250MG OF AMOXICILLIN) NET CONTENT OFIMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE USP (COMPACTED) EXTRADRY - 49.709KG (EXCL 2% WASTAGE))	1 Number	1	AMOXICILLIN TRIHYDRATE USP COMPACTED	292.639 mg.
MOXILEB -CV -625 TABLET USP.	1 Number	2	AMOXICILLIN	585.28 mg.

(AMOXICILLIN & CLAVULANATE POTASSIUM TABLETS USP625MG).(((EACH TABLET CONTAINING AMOXICILLIN TRIHYDRATE EQUIVALENT TO 500MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE USP COMPACTED) EXTRA DRY - 128.117KG (EXCL 2% WASTAGE))			TRIHYDRATE USP COMPACTED	
MOXILEB -CV -1000TABLET USP. (AMOXICILLIN & CLAVULANATE POTASSIUM TABLETS USP 1000MG) (((EACH TABLET CONTAINING AMOXICILLIN TRIHYDRATE EQUIVALENT TO 875MG OF AMOXICILLIN). NET CONTENT OFIMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE USP (COMPACTED) EXTRA DRY -238.359KG (EXCL 2% WASTAGE)	1 Number	3	AMOXICILLIN TRIHYDRATE USP COMPACTED	892.511 mg.
MOXILEB -CV -156.25 DRY SYRUP USP. (AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORALSUSPENSION USP 156.25MG/5ML)((EACH 5ML CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO 125MG OFAMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1AMOXICILLIN TRIHYDRATEUSP (COMPACTED) EXTRA DRY -44.083KG (EXCL 2% WASTAGE)) 60 ml Bottle.	1 Number	4	AMOXICILLIN TRIHYDRATE USP COMPACTED	1575.0 mg.

MOXILEB -CV -228.5 DRY SYRUP USP. (AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORALSUSPENSION USP 228.5 MG/5ML)((EACH 5ML CONTAINS AMOXICILLIN TRIHYDRATE EQUIVALENT TO 200MG OFAMOXICILLIN) . NET CONTENT OF IMPORT /EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATEUSP (COMPACTED) EXTRA DRY - 87.202KG (EACL 2% WASTAGE) 60 ml. Bottle.	1 Number	5	AMOXICILLIN TRIHYDRATE USP COMPACTED	2520.0 mg.
MOXILEB -CV -457 DRY SYRUP USP. (AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORALSUSPENSION USP 457MG/5ML)((EACH 5ML CONTIANS AMOXICILLIN TRIHYDRATE EQUIVALENT TO 400MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRIHYDRATE USP(COMPACTED) EXTRA DRY - 187.825KG (EXCL 2% WASTAGE) 70 ml. Bottle.	1 Number	6	AMOXICILLIN TRIHYDRATE USP COMPACTED	5880.0 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	89 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006087AM25
RA File Number	03AX04005733 AM25
Licence No and	0311041178/10/02/2025

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No. 0311032405 dated 21/03/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxycycline Hyclate DR Tablets USP 100 mg.	1 Number	1	Doxycycline Hyclate USP	115.40 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	90 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	ENALTEC LABS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00006117AM25			
RA File Number	03AX04005751 AM25			
Licence No and Date	0311041201/10/02/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sitagliptin Phosphate Monohydrate	1 kg.	1	3R)-3-AMINO-1-[3-TRIFLUOROMETHYL)-5,6,7,8- TETRAHYDRO-12,4TRIAZOLO [4,3-a]PYRAZIN-7-YL]-4-(2,4,5-TRIFLUOROPHENYL)BUTAN)	0.816 kg.

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

Case No.	91 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	ENALTEC LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006118AM25
RA File Number	03AX04005750 AM25
Licence No and Date	0311041202/10/02/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sitagliptin Phosphate Monohydrate	1 kg.	1	3R)-3-AMINO-1-[3-TRIFLUOROMETHYL)-5,6,7,8- TETRAHYDRO-12,4TRIAZOLO [4,3-a]PYRAZIN-7-YL]-4-(2,4,5-TRIFLUOROPHENYL)BUTAN)	0.816 kg.

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

Case No.	92 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	SHUKRA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006129AM25
RA File Number	08AX04001931 AM25
Licence No and	0811014061/11/02/2025

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Methyldopa Tablets 250 mg	1 Number	1	Methyldopa API	255 mg/Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	93 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006136AM25
RA File Number	03AX04005786 AM25
Licence No and Date	0311041215/11/02/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	94 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	CORAL DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006181AM25
RA File Number	05AX04003803 AM25
Licence No and Date	0511030866/12/02/2025
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Fluticasone Propionate (EP or BP or USP or IP)	1 kg.	1	8 DM	1.30 kg.

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

Case No.	95 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006182AM25
RA File Number	07AX04001888 AM25
Licence No and Date	0711013638/12/02/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jul/202526/6** dated 31/07/2025 against advance authorization No. 0711013126 dated 24/12/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Bromocriptine Tablets 2.5 mg	1 Number	1	Bromocriptine Mesilate BP/EP/IP/USP	2.927 mg/Tablet

NC also recommended to make a new SION for this export product.

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

Case No.	96 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	LEE PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006185AM25
RA File Number	09AX04001050 AM25
Licence No and Date	0911009037/12/02/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.** NC/3/MEET/Jun/202526/5 dated 30.06.2025 against advance authorization **No.** 0911008676 dated 20/12/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

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

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

Case No.	97 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006189AM25
RA File Number	08AX04001924 AM25
Licence No and Date	0811014088/12/02/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Phenylephrine Hydrochloride in 0.9 % Sodium Chloride Injection, 0.08 mg/mL (20 mg/250 mL)	1 Number	1	Phenylephrine HCl USP/Ph.Eur	21.00 mg.
Phenylephrine Hydrochloride in 0.9 % Sodium Chloride Injection, 0.16 mg/mL (40 mg/250 mL)	1 Number	2	Phenylephrine HCl USP/Ph.Eur	42.00 mg.
Phenylephrine Hydrochloride in 0.9 % Sodium Chloride Injection, 0.4 mg/mL (100 mg/250 mL)	1 Number	3	Phenylephrine HCl USP/Ph.Eur	105.00 mg.
Phenylephrine Hydrochloride Injection USP, 10 mg/mL (10 mL)	1 Number	4	Phenylephrine HCl USP/Ph.Eur	110.00 mg.
Phenylephrine Hydrochloride Injection USP, 10 mg/mL (5 mL)	1 Number	5	Phenylephrine HCl USP/Ph.Eur	55.00 mg.
Phenylephrine Hydrochloride Injection USP, 10 mg/mL (1 mL)	1 Number	6	Phenylephrine HCl USP/Ph.Eur	11.00 mg.

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

Case No.	98 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006194AM25
RA File Number	05AX04003930 AM25
Licence No and Date	0511030876/13/02/2025
Norms Committee Decision: The committee considered the request of firm for rfixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Separate Molecular required for Diethylene Glycol (DEG) and Dipropylene Glycol (DPG) in reaction details.	

Case No.	99 / NC/3/MEET/Sep/202526/8																
Case Status	Case Approved																
Party Name	KAWAKEN STERLING SURFACTANTS PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025																
HQ File Number	HQRNORM APPLY 00006208AM25																
RA File Number	03AX04000593 AM25																
Licence No and Date	0311041317/13/02/2025																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td rowspan="2">STERO CARE CMEA (Coco Mono Ethanol Amide)</td><td rowspan="2">235000 kg.</td><td>1</td><td>Fatty Acid (Kortacid CG)/(C1218HK)</td><td>200502 kg.</td></tr><tr><td>2</td><td>Mono Ethanol Amine (MEA)</td><td>55601 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	STERO CARE CMEA (Coco Mono Ethanol Amide)	235000 kg.	1	Fatty Acid (Kortacid CG)/(C1218HK)	200502 kg.	2	Mono Ethanol Amine (MEA)	55601 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
STERO CARE CMEA (Coco Mono Ethanol Amide)	235000 kg.	1	Fatty Acid (Kortacid CG)/(C1218HK)	200502 kg.													
		2	Mono Ethanol Amine (MEA)	55601 kg.													

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

Case No.	100 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006210AM25
RA File Number	05AX04003649 AM25
Licence No and Date	0511030885/13/02/2025
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant information / documents from the firm.	

Case No.	101 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	PANACEA BIOTEC PHARMA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00006212AM25			
RA File Number	05AX04003935 AM25			
Licence No and Date	0511030888/13/02/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Feb/202425/17 dated 25/02/2025 against advance authorization No. 0511021399 dated09/10/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Alphadol Capsules (Each Soft Gelatin Capsule Contains: Alfacalcidol 0.25 mcg.)	1 Number	1	Alfacalcidol	0.255 mcg.
Alphadol-CA Capsules((Each Soft Gelatin Capsule Contains: Alfacalcidol 0.25 mcg.&Calcium Carbonate 500 mg. equivalent to Elemental Calcium 200 mg.))	1 Number	2	Alfacalcidol	0.255 mcg.
Alphadol 1 mg (Each Soft Glatin Capsule Contains: Alfacalcidol 1.00 mcg.)	1 Number	3	Alfacalcidol	1.02 mcg.

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

Case No.	102 / NC/3/MEET/Sep/202526/8			
Case Status	Case Approved			
Party Name	PRACHEM LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025			
HQ File Number	HQRNORM APPLY 00006216AM25			
RA File Number	08AX04001958 AM25			
Licence No and Date	0811014102/13/02/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Triamcinolone Acetonide	1 kg.	1	9,11B-Epoxyde Triamcinolone (5TR)	1.00 kg.

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

Case No.	103 / NC/3/MEET/Sep/202526/8
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006218AM25
RA File Number	30AX04000658 AM25
Licence No and Date	3011006529/13/02/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.** NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 3011005627 dated 22/08/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
METHOTREXATE INJECTION USP (50 MG/2ML)(EACH ML CONTAINS: METHOTREXATE USP...25 MG, WATER FOR INJECTION USP...Q.S)	1 Number	1	Methotrexate	55.00 mg.
METHOTREXATE INJECTION USP (500 MG/5 ML)(EACH ML CONTAINS METHOTREXATE USP...100 MG, WATER FOR INJECTION USP...Q.S)	1 Number	2	Methotrexate	550.00 mg.
METHOTREXATE INJECTION USP (1000mg/10ml)(EACH ML CONTAINS: METHOTREXATE USP...100 MG, WATER FOR INJECTION USP...Q.S)	1 Number	3	Methotrexate	1100.00 mg.

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

Case No.	104 / NC/3/MEET/Sep/202526/8
Case Status	Case Deferred
Party Name	DECCAN NUTRACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025
HQ File Number	HQRNORM APPLY 00006568AM25
RA File Number	02AX04000733 AM25
Licence No and Date	0211008274/05/03/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Complete chemistry with molecular weight and percentage yield on molar basis.	

Case No.	105 / NC/3/MEET/Sep/202526/8													
Case Status	Case Approved													
Party Name	FINE ORGANIC INDUSTRIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202526/ 8 and 17/09/2025													
HQ File Number	HQRNORM APPLY 00001553AM26													
RA File Number	03AX04001307 AM26													
Licence No and Date	0311044903/18/06/2025													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td rowspan="2">Neutralized Amide Ester</td><td rowspan="2">1 kg.</td><td>1</td><td>Stearic Acid</td><td>0.95 kg.</td></tr><tr><td>2</td><td>Mono Ethanol Amine</td><td>0.056 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Neutralized Amide Ester	1 kg.	1	Stearic Acid	0.95 kg.	2	Mono Ethanol Amine	0.056 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Neutralized Amide Ester	1 kg.	1	Stearic Acid	0.95 kg.										
		2	Mono Ethanol Amine	0.056 kg.										

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