



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

रोड, नई दिल्ली

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

(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III**Meeting No -NC/3/MEET/Dec/202526/11****Meeting Date -18/12/2025**

Minutes of the Norms Committee–3 Meeting No.NC/3/MEET/Dec/202526/11 dated 18/12/2025 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 Raman Kumar, Deputy DGFT	DGFT (HQ)

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

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

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

Case No.	1 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000124AM26
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents from the firm: 1. Whether the export description is as per Drug Manufacturing Licence (DML)? 2. Copy of such DML.	

Case No.	2 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000125AM26
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed by the Committee the Advance Authorisation is 2009 and there is no import item is listed in Advance Authorisation, Therefore, 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.	3 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00001052AM26
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The representative of the firm attended the Personal Hearing and presented the case. The Committee considered the submissions made and, after due deliberation, advised the firm to furnish the net percentage wastage from rolls to finished product, separately for the upper and lower sides.	

Case No.	4 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	FINE ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00001277AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the firm's request for fixation of ad-hoc norms. However, it was observed that the firm, vide its letter dated 10.12.2025, requested withdrawal of the application. Accordingly, the Committee decided to close the firm's application.	

Case No.	5 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	PUROGENE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00006919AM25

RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete and Balanced chemical reactions with Molecular Weight. 2. Percentage Yield on Molar basis for each step. 3. Material balance for each step.	

Case No.	6 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	VIJAYASRI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	018305000961AM12
RA File Number	092404000478 AM12
Licence No and Date	0910051240/13/02/2012
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	7 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	SWEMED DIAGNOSTICS
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	018305000077AM15
RA File Number	072404000426 AM14
Licence No and Date	0710102252/20/02/2014
Norms Committee Decision: The Committee considered the case as per the agenda and observed that the firm has still not furnished the complete application along with the relevant documents. Accordingly, it was decided to grant one more opportunity to the firm to submit the complete application. The concerned RA may also be requested to forward the firm's application.	

Case No.	8 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	UNIJULES LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	018305000700AM15
RA File Number	039504000413 AM15
Licence No and Date	0310787952/12/08/2014
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case.	

Case No.	9 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00007896AM24
RA File Number	072404000347 AM16
Licence No and Date	0710109255/12/01/2016
Norms Committee Decision: NC decided to defer the case.	

Case No.	10 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00000398AM26
RA File Number	039404000726 AM18
Licence No and Date	0310817755/13/12/2017

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ipratropium Pressurised Inhalation 20 mcg / Ipravent 20 mcg Inhaler (200MD) (Ipramar 20mcg Inhaler / INFLUMIX 20MCG (200MD) with 63 mcl Aerosol Valve, 19ml Plasma Coated Aluminium Can with 0.48 mm Actuator HFA 227 Gas 21.30 gms)	1 Number	1	Ipratropium Bromide	4.00 mg.
		4	63 mcl AEROSOL VALVES	Relevant, as per Packing Policy and General Notes.
		7	19 ml Plasma Coated ALUMINIUM CAN	
		10	0.48 mm OD ACTUATORS WITH DUST COVERS / CAPS	
		13	Heptafluoropropane P227 Gas (HFA-227)	21.12 mg.
Ipratropium Pressurised Inhalation 40 mcg / Ipravent 40 mcg Inhaler (200MD) Ipramar 40 mcg Inhaler (with 63 mcl Aerosol Valve, 19 ml Plasma Coated Aluminium Can with 0.48 mm Actuator HFA 227 Gas 21.25 gms)	1 Number	2	Ipratropium Bromide	8.00 mg.
		5	63 mcl AEROSOL VALVES	Relevant, as per Packing Policy and General Notes.
		8	19 ml Plasma Coated ALUMINIUM CAN	
		11	0.48 mm OD ACTUATORS WITH DUST COVERS / CAPS	
		14	Heptafluoropropane P227 Gas	21.12 mg.
Ipratropium Bromide 20 mcg	1 Number	3	Ipratropium Bromide	4.00 mg.

and Salbutamol Sulphate 100 mcg Inhaler (200MD) DUOLIN INHALER (200MD) (with 63 mcl Aerosol Valve, 19 ml Plasma coated Aluminium Can with 0.58 mm Actuator HFA 227 Gas 21.10 gms)		6	63 mcl AEROSOL VALVES	Relevant, as per Packing Policy and General Notes.
		9	19 ml Plasma Coated ALUMINIUM CAN	
		12	0.58 mm OD ACTUATORS WITH DUST COVERS / CAPS	
		15	Heptafluoropropane P227 Gas	21.12 mg.

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

Case No.	11 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00000309AM26
RA File Number	292404000010 AM20
Licence No and Date	2910025424/19/08/2019
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.	12 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025

HQ File Number	HQRNORM REVIW00003939AM26
RA File Number	NA
Licence No and Date	0310837840/24/08/2020

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cyclaniliprole Technical 95.00% w/w min. (Cyclaniliprole (IKI-3106))	1 kg.	1	(BPPA)3-Bromo-4-chloro-1-(3-chloro-2-pyridyl)-2-[[{(1RS)-1-cyclopropylethyl} carbamoyl]pyrazole-5-carboxanilide	0.966 kg.
		2	Ethyl Acetate	1.72 kg.
		3	Bromine	0.40 kg.
		4	Caustic Soda	0.087 kg.
		5	Sulphuric Acid	0.04 kg.
		6	Sodium bicarbonate	0.081 kg.

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

Case No.	13 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00006674AM25
RA File Number	26AA04002063 AM22
Licence No and Date	2611000198/13/07/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
(S,E)-4-((tert-butyl dimethylsilyl)oxy)pent-2-enal	1346 kg.	1	L-Ethyl lactate	2000 kg.
		2	Imidazole	1400 kg.
		3	TBDMS Chloride	2040 kg.
		4	(Formylmethylene) triphenylphosphorane	4675 kg.
		5	Potassium sodium tartrate tetrahydrate	6250 kg.
		6	Heptane	8220 Litre

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

Case No.	14 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00192148AM22
RA File Number	03AA04091496 AM22
Licence No and Date	0311007180/23/09/2021

Norms Committee Decision:

The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the

absence of the required information and documents, the Committee decided to reject the case.

Case No.	15 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	ZIM LABORATORIES LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000002AM26
RA File Number	NA
Licence No and Date	5011000387/08/02/2022
Norms Committee Decision: The Committee observed that the firm has applied for authorization under the Self-Ratification Scheme in terms of para 4.06 of the FTP read with para 4.07A of the HBP, while simultaneously seeking fixation of norms under para 4.07 of the HBP. In view of the above, the NC decided to close the case and advised the firm as well as the concerned RA to take action in accordance with the relevant provisions of para 4.06 of the FTP and para 4.07A of the HBP.	

Case No.	16 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00001406AM25
RA File Number	03AX04000821 AM23
Licence No and Date	0311015467/13/06/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished the reply of deficiency letter. Hence, the Committee decided to give one more opportunity to furnish the required documents.	

Case No.	17 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	GLENMARK PHARMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00006545AM25
RA File Number	03AX04001157 AM23
Licence No and Date	0311015490/14/06/2022
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	18 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	SUDEEP PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00002560AM23
RA File Number	34AX04000414 AM23
Licence No and Date	3411002630/10/08/2022
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case.	

Case No.	19 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00004443AM23
RA File Number	34AX04000759 AM23
Licence No and Date	3411003012/18/11/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished	

the reply of deficiency letter. Hence, the Committee decided to give one more opportunity to furnish the required documents.

Case No.	20 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	DELTA FINOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00004995AM23
RA File Number	03AX04004505 AM23
Licence No and Date	0311019991/15/12/2022
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case.	

Case No.	21 / NC/3/MEET/Dec/202526/11			
Case Status	Case Approved			
Party Name	SCOTT EDIL PHARMACIA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025			
HQ File Number	HQRNORM REVIW00000095AM26			
RA File Number	30AX04000539 AM23			
Licence No and Date	3011003243/07/03/2023			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-				

Nystatin Oral Suspension USP 100000 IU/ML (Each 1ML suspension contain : Nystatin USP 100000 IU in flover base q.s. Colour : Colour base approved) (30 ML Bottle contains 100000 IU/ML & 100000 IU = 3 mg) (Net content of Nystatin not less than 2900 Kgs))	3222222 Numbers	1	Nystatin USP (Potency 3333 IU/mg.)	3045.0 kg.
		2	Sucralose	2552.0 kg.

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

Case No.	22 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	MEONE HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00000082AM26
RA File Number	04AX04000118 AM24
Licence No and Date	0411005383/10/05/2023
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	23 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	SATYADEVA PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000775AM24
RA File Number	09AX04000090 AM24
Licence No and	0911005025/11/05/2023

Date	
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case.	

Case No.	24 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	SARAL CHEMTECH LLP
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000865AM24
RA File Number	33AX04000105 AM23
Licence No and Date	3311001206/16/05/2023
Norms Committee Decision: The firm was called for Personal Hearing on 18.12.2025 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for <u>Personal Hearing</u> with relevant documents/information.	

Case No.	25 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000950AM24
RA File Number	09AX04000137 AM24
Licence No and Date	0911005059/18/05/2023
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case.	

Case No.	26 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	OAN INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00001150AM24
RA File Number	13AX04000047 AM24
Licence No and Date	1311001965/26/05/2023
Norms Committee Decision: The firm was called for Personal Hearing on 18.12.2025 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for <u>Personal Hearing</u> with relevant documents/information.	

Case No.	27 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	SHREE GANESH REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00001244AM24
RA File Number	34AX04000140 AM24
Licence No and Date	3411003769/01/06/2023
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case.	

Case No.	28 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	UNIMAX LABORATORIES
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025

HQ File Number	HQRNORM REVIW00000489AM26
RA File Number	05AX04000673 AM24
Licence No and Date	0511019298/12/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Azithromycin Tablets 250 mg IP(Each tablet contains : Azithromycin IP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	1	Azithromycin Dihydrate IP	267.27 mg.
Azithromycin Tablets 500 mg IP(Each tablet contains : Azithromycin IP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	2	Azithromycin Dihydrate IP	534.54 mg.
Spiramycin Tablets 1.5 MIU(Each tablet contains Spiramycin EP 1.5 million i.u. Eq. to (379.12 mg / tablet))	1 Number	3	Spiramycin EP	373.02 mg.
Spiramycin Tablets 3.0 MIU(Each tablet contains Spiramycin EP 1.5 million i.u. Eq. to (758.24 mg / tablet))	1 Number	4	Spiramycin EP	746.04 mg.
Azithromycin Tablets 250 mg USP(Each tablet contains : Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	5	Azithromycin Dihydrate USP	267.27 mg.
Azithromycin Tablets 500 mg USP(Each tablet contains : Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	6	Azithromycin Dihydrate USP	534.54 mg.

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

Case No.	29 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	ARCH PROTECTION CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00001705AM24
RA File Number	03AX04001182 AM24
Licence No and Date	0311024600/16/06/2023
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case.	

Case No.	30 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	BULI CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00006792AM25
RA File Number	03AX04001475 AM24
Licence No and Date	0311025181/06/07/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. To indicate the exact percentage of Hexane in export item, because the requirement of raw materials will be different in different concentration. 2. Complete chemical reaction of reactant and product indicating molecular weight of each chemical and yield of the reaction and accordingly calculate the requirement.	

3. The commercial value of by-product Lithium Chloride, supported by invoices.
4. Stoichiometric material balance of the reaction.

To indicate indigenous items in Annexure to Appendix-4E.

Case No.	31 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00004796AM24
RA File Number	34AX04000209 AM24
Licence No and Date	3411003978/02/08/2023
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case.	

Case No.	32 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00004944AM24
RA File Number	07AX04000704 AM24
Licence No and Date	0711008930/09/08/2023
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case.	

Case No.	33 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	INTIGREAT CONSULTING SERVICES LLP
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00006403AM24
RA File Number	03AX04003028 AM24
Licence No and Date	0311028103/23/10/2023
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case.	

Case No.	34 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	SANDOZ PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00006418AM24
RA File Number	03AX04003201 AM24
Licence No and Date	0311028115/23/10/2023
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case. .	

Case No.	35 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025

and Date	
HQ File Number	HQRNORM REVIW00000250AM26
RA File Number	03AX04004064 AM24
Licence No and Date	0311029280/12/12/2023
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, the committee didn't find any merit to review the norms and it was decided to reject the case maintaining the status quo.	

Case No.	36 / NC/3/MEET/Dec/202526/11			
Case Status	Case Approved			
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025			
HQ File Number	HQRNORM REVIW00006578AM25			
RA File Number	03AX04003989 AM24			
Licence No and Date	0311029847/03/01/2024			
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:-				

Case No.	37 / NC/3/MEET/Dec/202526/11
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Case Status	Case Deferred
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00007770AM24
RA File Number	09AX04000867 AM24
Licence No and Date	0911006493/05/01/2024
Norms Committee Decision: The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the firm was advised to get the Advanced Authorisation amended to show each export item separately with corresponding import.	

Case No.	38 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00007813AM24
RA File Number	03AX04004498 AM24
Licence No and Date	0311029998/08/01/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case.	

Case No.	39 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00007862AM24
RA File Number	07AX04001619 AM24
Licence No and Date	0711010173/10/01/2024
Norms Committee Decision:	

The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities being provided. In the absence of the required information and documents, the Committee decided to reject the case and firm has advised to pay customs duty on import items and regularize the case.

Case No.	40 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00007864AM24
RA File Number	07AX04001614 AM24
Licence No and Date	0711010175/10/01/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per the extant provisions.	

Case No.	41 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	SANPRAS HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00008015AM24
RA File Number	31AX04000283 AM24
Licence No and Date	3111003005/17/01/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per	

the extant provisions.

Case No.	42 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	PRASOL CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00008287AM24
RA File Number	03AX04004987 AM24
Licence No and Date	0311030614/01/02/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per the extant provisions.	

Case No.	43 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	LOZEN PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00008339AM24
RA File Number	03AX04004941 AM24
Licence No and Date	0311030679/05/02/2024
Norms Committee Decision: The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the firm was advised to submit the following documents: 1. Copy of AYUSH licence with approved composition.	

2. Copy of Master-Batch Formula showing net content of inputs in export.

Case No.	44 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00008383AM24
RA File Number	07AX04001749 AM24
Licence No and Date	0711010420/06/02/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per the extant provisions.	

Case No.	45 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00006623AM25
RA File Number	05AX04003618 AM24
Licence No and Date	0511023881/09/02/2024
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.	46 / NC/3/MEET/Dec/202526/11
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Case Status	Case Approved										
Party Name	CATION PHARMA										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025										
HQ File Number	HQRNORM APPLY 00008519AM24										
RA File Number	52AX04000341 AM24										
Licence No and Date	5211007357/12/02/2024										
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>Alendronate Sodium USP</td><td>1 kg.</td><td>1</td><td>Gamma Aminobutyric Acid</td><td>0.50 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Alendronate Sodium USP	1 kg.	1	Gamma Aminobutyric Acid	0.50 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Alendronate Sodium USP	1 kg.	1	Gamma Aminobutyric Acid	0.50 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	47 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	YELLOWSTONE FINE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
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 decided that a report may be called for from the concerned RA on whether the firm has transferred its name from <i>Yellowstone Fine Chemicals Private Limited</i> to <i>M/s Laxmi Organic Industries</i> in the IEC and other relevant documents, within thirty days from the date of receipt of the letter from DGFT (HQ).	

Case No.	48 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
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 agenda and it was decided that the firm may be advised to submit the statement of weighted average of potency/assy of each import consignment relevant to Bill of Entry.	

Case No.	49 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00008826AM24
RA File Number	03AX04005194 AM24
Licence No and Date	0311031599/29/02/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per the extant provisions.	

Case No.	50 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00009169AM24
RA File Number	03AX04005784 AM24
Licence No and Date	0311032244/16/03/2024

Norms Committee Decision:

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

1. As per chemical route synthesis and molecular weight given required of EDTA Acid should be 0.79 kg./kg. while import is 0.74 kg/kg and EDTA Acid is also shown as indigenous.
2. Please indicate whether export is Anhydrous or Tri-Hydrate.
3. Indicate percentage yield of reaction.

Case No.	51 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00009206AM24
RA File Number	03AX04005785 AM24
Licence No and Date	0311032328/19/03/2024

Norms Committee Decision:

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

1. Complete chemical reaction with molecular weight and structural formula and stagewise percentage yield on molar basis.
2. As per process of manufacture Methyl Iodide is used while import is only Iodine please explain.

Case No.	52 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00003616AM26
RA File Number	03AX04000127 AM25
Licence No and Date	0311033003/15/04/2024

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.	53 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000268AM25
RA File Number	09AX04001014 AM24
Licence No and Date	0911007079/16/04/2024
Norms Committee Decision: The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the firm was advised to get the Advanced Authorisation amended to show each export item separately with corresponding import.	

Case No.	54 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	SIGNATURE PHYTOCHEMICAL INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000467AM25
RA File Number	03AX04000380 AM25
Licence No and Date	0311033435/29/04/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per the extant provisions.	

Case No.	55 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	SANPRAS HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000523AM25
RA File Number	31AX04000022 AM25
Licence No and Date	3111003394/02/05/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per the extant provisions.	

Case No.	56 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000535AM25
RA File Number	03AX04000486 AM25
Licence No and Date	0311033558/03/05/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per the extant provisions.	

Case No.	57 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	HEMA DYECHEM PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000568AM25
RA File Number	03AX04000390 AM25
Licence No and Date	0311033616/06/05/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm has surrendered the Advance Authorisation to RA, Mumbai, therefore, it was decided to close the application of the firm.	

Case No.	58 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000733AM25
RA File Number	03AX04000685 AM25
Licence No and Date	0311033879/15/05/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per the extant provisions.	

Case No.	59 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000747AM25
RA File Number	07AX04000241 AM25
Licence No and Date	0711011310/16/05/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to	

the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per the extant provisions.

Case No.	60 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00000261AM26
RA File Number	03AX04000940 AM25
Licence No and Date	0311034134/27/05/2024
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.	61 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	MANIPAL NATURAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000966AM25
RA File Number	07AX04000258 AM25
Licence No and Date	0711011405/28/05/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per the extant provisions.	

Case No.	62 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	AGIO PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000990AM25
RA File Number	03AX04000815 AM25
Licence No and Date	0311034218/29/05/2024
Norms Committee Decision: The Committee considered the case as per the agenda and noted that the firm has failed to furnish a reply to the deficiency letter despite repeated reminders and adequate opportunities having been provided. In the absence of the requisite information and documents, the Committee decided to reject the case. The firm was accordingly advised to pay the applicable customs duty on the imported items and regularize the case as per the extant provisions.	

Case No.	63 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00000109AM26
RA File Number	09AX04000169 AM25
Licence No and Date	0911007440/18/06/2024
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.	64 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025

HQ File Number	HQRNORM REVIW00006669AM25
RA File Number	03AX04001750 AM25
Licence No and Date	0311035328/10/07/2024
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.	65 / NC/3/MEET/Dec/202526/11																
Case Status	Case Approved																
Party Name	HIKAL LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025																
HQ File Number	HQRNORM APPLY 00001886AM26																
RA File Number	NA																
Licence No and Date	0311036222/09/08/2024																
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/Nov/202526/10 dated 14/11/2025 against advance authorization No. 0311026196 dated 10/08/2023, 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:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="3">IKI-3106 (Cyclaniliprole)</td><td rowspan="3">1 kg.</td><td>1</td><td>3-Picoline</td><td>0.170 kg.</td></tr><tr><td>2</td><td>Mesylchloride</td><td>0.247 kg.</td></tr><tr><td>3</td><td>Sodium sulfite</td><td>0.105 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	IKI-3106 (Cyclaniliprole)	1 kg.	1	3-Picoline	0.170 kg.	2	Mesylchloride	0.247 kg.	3	Sodium sulfite	0.105 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
IKI-3106 (Cyclaniliprole)	1 kg.	1	3-Picoline	0.170 kg.													
		2	Mesylchloride	0.247 kg.													
		3	Sodium sulfite	0.105 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	66 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00002626AM25
RA File Number	05AX04001408 AM25
Licence No and Date	0511027294/21/08/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it has been observed that details given by the firms does not related to present case, therefore, it was decided to call for following information/documents from the firm:- 1. Complete technical details as per Annexure to Appendix-4E.	

Case No.	67 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	DR.ACHARYA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM REVIW00003204AM26
RA File Number	03AX04002498 AM25
Licence No and Date	0311036513/21/08/2024
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.	68 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025

and Date	
HQ File Number	HQRNORM APPLY 00003178AM25
RA File Number	05AX04001863 AM25
Licence No and Date	0511027857/20/09/2024
Norms Committee Decision: The Committee considered the case as per the agenda and decided to call the firm for a Personal Hearing before the Norms Committee to explain its case and submit the relevant information/documents. The officer attending the Personal Hearing on behalf of the firm shall not be below the rank of Vice President.	

Case No.	69 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00003321AM25
RA File Number	05AX04002052 AM25
Licence No and Date	0511028003/27/09/2024
Norms Committee Decision: The Committee considered the case as per the agenda and decided to call the firm for a Personal Hearing before the Norms Committee to explain its case and submit the relevant information/documents. The officer attending the Personal Hearing on behalf of the firm shall not be below the rank of Vice President.	

Case No.	70 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	ZENITH DYEINTERMEDIATES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00003609AM26
RA File Number	NA
Licence No and Date	0311037563/01/10/2024
Norms Committee Decision: 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.
NAS-5((2-DIAZO-1-NAPTHOL-5-SULFONIC ACID, SODIUM SALT))	1 kg.	1	TOBIAS ACID (PURITY MIN. 97%)	0.70 kg.

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

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

Case No.	71 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	ZENITH DYEINTERMEDIATES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00003606AM26
RA File Number	NA
Licence No and Date	0311041411/17/02/2025

Norms Committee Decision:

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.
NAS-5((2-DIAZO-1-NAPTHOL-5-SULFONIC ACID, SODIUM SALT))	1 kg.	1	TOBIAS ACID (PURITY MIN. 97%)	0.70 kg.

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

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

Case No.	72 / NC/3/MEET/Dec/202526/11													
Case Status	Case Approved													
Party Name	DECCAN NUTRACEUTICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025													
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 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>Nalbuphine Hydrochloride</td><td>1 kg.</td><td>1</td><td>Noroxymorphone Base</td><td>0.97 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Nalbuphine Hydrochloride	1 kg.	1	Noroxymorphone Base	0.97 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Nalbuphine Hydrochloride	1 kg.	1	Noroxymorphone Base	0.97 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	73 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00006921AM25
RA File Number	03AX04006549 AM25
Licence No and Date	0311042606/27/03/2025
Norms Committee Decision:	
The firm was granted an Advance Authorisation for the export product “ <i>COUMARIN</i> ” under Para 4.07 of the Handbook of Procedures (HBP). However, as per Para 4.11(b) of the Foreign Trade Policy (FTP) 2023, products falling under the category of perfume or perfumery compounds are ineligible for authorisation under Para 4.07 and are mandatorily required to be	

processed under Para 4.06 of the HBP.

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

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

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

Case No.	74 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00006923AM25
RA File Number	05AX04004435 AM25
Licence No and Date	0511031629/27/03/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Dec/202425/13 dated 07/01/2025 against advance authorization No. 0511026676 dated 15/07/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cyclomed Eye Drops 1% 5ml (Each ml contains 10 mg of Cyclopentolate Hydrochloride)	1 Pack	1	Cyclopentolate HCL USP	51.00 mg.

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

Case No.	75 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	DCM NOUVELLE SPECIALTY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00006926AM25
RA File Number	05AX04004410 AM25
Licence No and Date	0511031632/27/03/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	76 / NC/3/MEET/Dec/202526/11										
Case Status	Case Approved										
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025										
HQ File Number	HQRNORM APPLY 00006929AM25										
RA File Number	05AX04004368 AM25										
Licence No and Date	0511031633/27/03/2025										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Budesonide Inhalation Suspension 0.25 mg /2ml (Each ml contains Budesonide 0.125 mg) (Equivalent to 6.049 Kg of Bulk Drug))</td><td>1 Number</td><td>1</td><td>Budesonide</td><td>0.2625 mg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Budesonide Inhalation Suspension 0.25 mg /2ml (Each ml contains Budesonide 0.125 mg) (Equivalent to 6.049 Kg of Bulk Drug))	1 Number	1	Budesonide	0.2625 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Budesonide Inhalation Suspension 0.25 mg /2ml (Each ml contains Budesonide 0.125 mg) (Equivalent to 6.049 Kg of Bulk Drug))	1 Number	1	Budesonide	0.2625 mg							

Budesonide Inhalation Suspension 0.5 mg /2ml (Each ml contains Budesonide 0.25 mg) (Equivalent to 10.350 Kg of Bulk Drug)	1 Number	2	Budesonide	0.525 mg.
Budesonide Inhalation Suspension 1 mg /2ml (Each ml contains Budesonide 0.5 mg) (Equivalent to 9.600 Kg of Bulk Drug) (Total 25.999 Kg of Bulk Drug))	1 Number	3	Budesonide	1.05 mg.

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

Case No.	77 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00006934AM25
RA File Number	03AX04006615 AM25
Licence No and Date	0311042619/28/03/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Oct/202526/9 dated 14/10/2025 against advance authorization No. 0311042441 dated 24/03/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed.
Lumefantrine	1 Kg.	1	9H Fluorene	0.814 Kg.
		2	DI N Butylamine	0.390 Kg.
		3	Sodium Borohydride	0.040 Kg.

		4	Para Chloro Benzaldehyde	0.336 Kg.
		5	Di Methyl Formamide	0.555 Kg.

RA Concerned May Take Further Necessary Action As Per Above Decision Of NC.

Case No.	78 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	AGSON GLOBAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00006936AM25
RA File Number	05AX04004317 AM25
Licence No and Date	0511031656/28/03/2025
Norms Committee Decision: The firm was granted an Advance Authorisation for the export product “<i>CIS3 Hexenol-Bio Synthetic</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.	79 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	LAXAI LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00006945AM25
RA File Number	09AX04001195 AM25
Licence No and Date	0911009324/28/03/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	80 / NC/3/MEET/Dec/202526/11										
Case Status	Case Approved										
Party Name	BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025										
HQ File Number	HQRNORM APPLY 00006951AM25										
RA File Number	03AX04006612 AM25										
Licence No and Date	0311042664/29/03/2025										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Meropenem 1000 mg Powder for Solution for Injection or Infusion / Meropenem Injection 1 gm USP (Net Content Meropenem and Sodium Carbonate 200 kgs.</td><td>1 Number Vial</td><td>1</td><td>Meropenem and Sodium Carbonate (Sterile Bulk) / Meropenem For Injection USP)</td><td>1.255 gm/Vial</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Meropenem 1000 mg Powder for Solution for Injection or Infusion / Meropenem Injection 1 gm USP (Net Content Meropenem and Sodium Carbonate 200 kgs.	1 Number Vial	1	Meropenem and Sodium Carbonate (Sterile Bulk) / Meropenem For Injection USP)	1.255 gm/Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Meropenem 1000 mg Powder for Solution for Injection or Infusion / Meropenem Injection 1 gm USP (Net Content Meropenem and Sodium Carbonate 200 kgs.	1 Number Vial	1	Meropenem and Sodium Carbonate (Sterile Bulk) / Meropenem For Injection USP)	1.255 gm/Vial							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	81 / NC/3/MEET/Dec/202526/11																
Case Status	Case Approved																
Party Name	GALAXY SURFACTANTS LTD																
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025																
HQ File Number	HQRNORM APPLY 00006965AM25																
RA File Number	03AX04006624 AM25																
Licence No and Date	0311042693/30/03/2025																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Sodium Lauroyl Methyl Taurate (Galsoft SLT (N) / Galsoft SLT (N) MB)</td><td rowspan="2">1 kg.</td><td>1</td><td>Lauric Acid/ Lauric Acid C1299/ Lauric acid MB/ Lauric Acid C1299 MB</td><td>0.614 kg.</td></tr><tr><td>2</td><td>N-Methyl Taurine Sodium Salt 62%.</td><td>0.728 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sodium Lauroyl Methyl Taurate (Galsoft SLT (N) / Galsoft SLT (N) MB)	1 kg.	1	Lauric Acid/ Lauric Acid C1299/ Lauric acid MB/ Lauric Acid C1299 MB	0.614 kg.	2	N-Methyl Taurine Sodium Salt 62%.	0.728 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Sodium Lauroyl Methyl Taurate (Galsoft SLT (N) / Galsoft SLT (N) MB)	1 kg.	1	Lauric Acid/ Lauric Acid C1299/ Lauric acid MB/ Lauric Acid C1299 MB	0.614 kg.													
		2	N-Methyl Taurine Sodium Salt 62%.	0.728 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	82 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	PARAGON FINE AND SPECIALITY CHEMICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000004AM26
RA File Number	08AX04002207 AM25
Licence No and Date	0811014582/01/04/2025
Norms Committee Decision:	

The committee considered the 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, stichiometric balance on molar basis with molecular weight and percentage yield for each step of reaction

Case No.	83 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	PARAGON FINE AND SPECIALITY CHEMICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000005AM26
RA File Number	08AX04002208 AM25
Licence No and Date	0811014583/01/04/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	84 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000007AM26
RA File Number	03AX04006652 AM25
Licence No and Date	0311042725/01/04/2025
Norms Committee Decision:	
The firm was granted an Advance Authorisation for the export product “<i>Indomeran (Galaxmeran)</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.	85 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	PANACEA BIOTEC PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000013AM26
RA File Number	05AX04004470 AM25
Licence No and Date	0511031696/01/04/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Sep/202526/8 dated 17/09/2025 against advance authorization No. 0511030888 dated 13/02/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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: Alfalcidol 1.00 mcg.)	1 Number	3	Alfalcidol	1.02 mcg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	86 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	SANOFI CONSUMER HEALTHCARE INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000014AM26
RA File Number	03AX04006677 AM25
Licence No and Date	0311042739/01/04/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Jul/202526/6 dated 31/07/2025 against advance authorization No. 0311039854 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.
Festal Dragees (Tablets) Enterosolube 10 x 10s ((Total Net Weight of Pancreatin 3738.32 Kgs Strength of Pancreatin 192 mg/Tablet))	1 Number Tablet	1	Pancreatin	195.84 mg

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

Case No.	87 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	HI-PURITY CHEMICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025													
HQ File Number	HQRNORM APPLY 00000015AM26													
RA File Number	03AX04006708 AM25													
Licence No and Date	0311042741/01/04/2025													
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>Halquinol</td> <td>1 kg.</td> <td>1</td> <td>8 Hydroxyquinoline</td> <td>0.77 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.	Halquinol	1 kg.	1	8 Hydroxyquinoline	0.77 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Halquinol	1 kg.	1	8 Hydroxyquinoline	0.77 kg.										

Case No.	88 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	AZAKEM LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000017AM26
RA File Number	09AX04001123 AM25
Licence No and Date	0911009334/01/04/2025
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	89 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025

HQ File Number	HQRNORM APPLY 00000026AM26																																	
RA File Number	05AX04004491 AM25																																	
Licence No and Date	0511031702/02/04/2025																																	
Norms Committee Decision:																																		
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Sep/202526/8 dated 17/09/2025 against advance authorization No. 3411002586 dated 29/07/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																																		
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Doxepin Hydrochloride Capsules USP 10 mg.</td><td>1 Number</td><td>1</td><td>Doxepin HCL</td><td>11.353 mg.</td></tr><tr><td>Doxepin Hydrochloride Capsules USP 25 mg</td><td>1 Number</td><td>2</td><td>Doxepin HCL</td><td>28.384 mg.</td></tr><tr><td>Doxepin Hydrochloride Capsules USP 50 mg</td><td>1 Number</td><td>3</td><td>Doxepin HCL</td><td>56.766 mg.</td></tr><tr><td>Doxepin Hydrochloride Capsules USP 75 mg</td><td>1 Number</td><td>4</td><td>Doxepin HCL</td><td>85.152 mg.</td></tr><tr><td>Doxepin Hydrochloride Capsules USP 100 mg</td><td>1 Number</td><td>5</td><td>Doxepin HCL</td><td>113.538 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Doxepin Hydrochloride Capsules USP 10 mg.	1 Number	1	Doxepin HCL	11.353 mg.	Doxepin Hydrochloride Capsules USP 25 mg	1 Number	2	Doxepin HCL	28.384 mg.	Doxepin Hydrochloride Capsules USP 50 mg	1 Number	3	Doxepin HCL	56.766 mg.	Doxepin Hydrochloride Capsules USP 75 mg	1 Number	4	Doxepin HCL	85.152 mg.	Doxepin Hydrochloride Capsules USP 100 mg	1 Number	5	Doxepin HCL	113.538 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																														
Doxepin Hydrochloride Capsules USP 10 mg.	1 Number	1	Doxepin HCL	11.353 mg.																														
Doxepin Hydrochloride Capsules USP 25 mg	1 Number	2	Doxepin HCL	28.384 mg.																														
Doxepin Hydrochloride Capsules USP 50 mg	1 Number	3	Doxepin HCL	56.766 mg.																														
Doxepin Hydrochloride Capsules USP 75 mg	1 Number	4	Doxepin HCL	85.152 mg.																														
Doxepin Hydrochloride Capsules USP 100 mg	1 Number	5	Doxepin HCL	113.538 mg.																														
RA concerned may take further necessary action as per above decision of NC.																																		

Case No.	90 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000042AM26
RA File Number	05AX04004489 AM25
Licence No and Date	0511031710/02/04/2025
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.
Tobramycin Inhalation Solution, 300 mg / 4ml	1 Number Pack	1	Tobramycin USP	315 mg./Vial
Tobramycin Inhalation Solution, 300 mg / 5ml	1 Number Pack	2	Tobramycin USP	315 mg./Vial

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

Case No.	91 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	VIJAYASRI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000053AM26
RA File Number	09AX04001141 AM25
Licence No and Date	0911009349/02/04/2025

Norms Committee Decision:

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

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

Case No.	92 / NC/3/MEET/Dec/202526/11
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Case Status	Case Approved										
Party Name	MICRO LABS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025										
HQ File Number	HQRNORM APPLY 00000072AM26										
RA File Number	07AX04002128 AM25										
Licence No and Date	0711014085/02/04/2025										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Cromolyn Sodium Oral Concentrate Solution (100 mg / 5 ml) 5 ml Net Contents: 1685.491 kg))</td><td>1 Number</td><td>1</td><td>Cromolyn Sodium (Sodium Cromoglycate) BP/EP/USP)</td><td>0.102 gm.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Cromolyn Sodium Oral Concentrate Solution (100 mg / 5 ml) 5 ml Net Contents: 1685.491 kg))	1 Number	1	Cromolyn Sodium (Sodium Cromoglycate) BP/EP/USP)	0.102 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Cromolyn Sodium Oral Concentrate Solution (100 mg / 5 ml) 5 ml Net Contents: 1685.491 kg))	1 Number	1	Cromolyn Sodium (Sodium Cromoglycate) BP/EP/USP)	0.102 gm.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	93 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	PARAGON FINE AND SPECIALITY CHEMICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000076AM26
RA File Number	08AX04002246 AM25
Licence No and Date	0811014626/03/04/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	94 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	PRIGIV SPECIALTIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000080AM26
RA File Number	03AX04006649 AM25
Licence No and Date	0311042828/03/04/2025

Norms Committee Decision:

The firm was granted an Advance Authorisation for the export product “*Luzerny Butyrate*” 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.	95 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	PRIGIV SPECIALTIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000081AM26
RA File Number	03AX04006648 AM25
Licence No and Date	0311042829/03/04/2025

Norms Committee Decision:

The firm was granted an Advance Authorisation for the export product “*Luzerny Benzoate*”

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

Case No.	96 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000084AM26
RA File Number	03AX04006667 AM25
Licence No and Date	0311042834/03/04/2025
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
1. Copy of Drug Manufacturing Licence (DML) showing approved composition for each export item. 2. Copy of Master-Batch Formula for each export item showing net content of each input.	

Case No.	97 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	VINDHYA ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025

HQ File Number	HQRNORM APPLY 00000085AM26																						
RA File Number	09AX04001193 AM25																						
Licence No and Date	0911009362/03/04/2025																						
Norms Committee Decision:																							
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																							
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="4">Amino Carbinol Tartrate</td><td rowspan="4">1 kg.</td><td>1</td><td>2-AZABICYCLO (2.2.1) HEPT-5-EN-3-ONE (VINCELACTAM)</td><td>1.18 kg.</td></tr><tr><td>2</td><td>SODIUM BOROHYDRIDE POWDER</td><td>0.214 kg.</td></tr><tr><td>3</td><td>D(-) TARTARIC ACID</td><td>0.742 kg.</td></tr><tr><td>4</td><td>L + TARTARIC ACID</td><td>0.90 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Amino Carbinol Tartrate	1 kg.	1	2-AZABICYCLO (2.2.1) HEPT-5-EN-3-ONE (VINCELACTAM)	1.18 kg.	2	SODIUM BOROHYDRIDE POWDER	0.214 kg.	3	D(-) TARTARIC ACID	0.742 kg.	4	L + TARTARIC ACID	0.90 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																			
Amino Carbinol Tartrate	1 kg.	1	2-AZABICYCLO (2.2.1) HEPT-5-EN-3-ONE (VINCELACTAM)	1.18 kg.																			
		2	SODIUM BOROHYDRIDE POWDER	0.214 kg.																			
		3	D(-) TARTARIC ACID	0.742 kg.																			
		4	L + TARTARIC ACID	0.90 kg.																			
RA concerned may take further necessary action as per above decision of NC.																							

Case No.	98 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000110AM26
RA File Number	03AX04000032 AM26
Licence No and Date	0311042878/05/04/2025
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/2 dated 08/05/2025 against advance authorization No. 0311037559 dated 01/10/2024, it was decided to fix ad-hoc norms under Para 4.07 of	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Co-codamol 8/500 tablets (Codeine Phosphate Hemihydrate 8 mg and Paracetamol 500mg) (Each Tablet contains Codeine Phosphate Hemihydrate 8 mg and Paracetamol 500 mg (Net Wt. Codeine Phosphate Hemihydrate 768.00 KGS))	1 Number	1	Codeine Phosphate Hemihydrate	8.16 mg.
Co-codamol 15/500 tablets (Codeine Phosphate Hemihydrate 15 mg and Paracetamol 500 mg) (Each Tablet contains Codeine Phosphate Hemihydrate 15mg and Paracetamol 500 mg (Net Wt. Codeine Phosphate Hemihydrate 1353.60 KGS))	1 Number	2	Codeine Phosphate Hemihydrate	15.30 mg.
Co-codamol 30/500 tablets (Codeine Phosphate Hemihydrate 30 mg and Paracetamol 500 mg) (Each Tablet contains Codeine Phosphate Hemihydrate 30mg and Paracetamol 500 mg (Net Wt. Codeine Phosphate Hemihydrate 2707.20 KGS))	1 Number	3	Codeine Phosphate Hemihydrate	30.60 mg.

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

Case No.	99 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000111AM26
RA File Number	03AX04000038 AM26
Licence No and	0311042879/05/04/2025

Date

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/2 dated 08/05/2025 against advance authorization No. 0311037559 dated 01/10/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Co-codamol 8/500 tablets (Codeine Phosphate Hemihydrate 8 mg and Paracetamol 500mg) (Each Tablet contains Codeine Phosphate Hemihydrate 8 mg and Paracetamol 500 mg (Net Wt. Codeine Phosphate Hemihydrate 768.00 KGS))	1 Number	1	Codeine Phosphate Hemihydrate	8.16 mg.
Co-codamol 15/500 tablets (Codeine Phosphate Hemihydrate 15 mg and Paracetamol 500 mg) (Each Tablet contains Codeine Phosphate Hemihydrate 15mg and Paracetamol 500 mg (Net Wt. Codeine Phosphate Hemihydrate 1353.60 KGS))	1 Number	2	Codeine Phosphate Hemihydrate	15.30 mg.
Co-codamol 30/500 tablets (Codeine Phosphate Hemihydrate 30 mg and Paracetamol 500 mg) (Each Tablet contains Codeine Phosphate Hemihydrate 30mg and Paracetamol 500 mg (Net Wt. Codeine Phosphate Hemihydrate 2707.20 KGS))	1 Number	3	Codeine Phosphate Hemihydrate	30.60 mg.

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

Case No.	100 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025

and Date	
HQ File Number	HQRNORM APPLY 00000127AM26
RA File Number	07AX04000018 AM26
Licence No and Date	0711014131/08/04/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	101 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000132AM26
RA File Number	09AX04001189 AM25
Licence No and Date	0911009400/08/04/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0911007746 dated 16/08/2024, 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.
Amlodipine and Benazepril Hydrochloride Capsules USP 2.5 mg / 10 mg (Pack size:100s) (Consists of 08 Kgs of Benazepril Hydrochloride USP	1 Number	1	Benazepril Hydrochloride USP	10.2 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 05 mg / 10 mg (Pack size:100s) (Consists of 56 Kgs of Benazepril Hydrochloride USP	1 Number	2	Benazepril Hydrochloride USP	10.2 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 05 mg / 10 mg (Pack size:500s) (Consists of 14 Kgs of	1 Number	3	Benazepril Hydrochloride USP	10.2 mg.

Benazepril Hydrochloride USP				
Amlodipine and Benazepril Hydrochloride Capsules USP 05 mg / 20 mg (Pack size:100s) (Consists of 224 Kgs of Benazepril Hydrochloride USP	1 Number	4	Benazepril Hydrochloride USP	20.4 mg.,
Amlodipine and Benazepril Hydrochloride Capsules USP 05 mg / 20 mg (Pack size:500s) (Consists of 28 Kgs of Benazepril Hydrochloride USP	1 Number	5	Benazepril Hydrochloride USP	20.4 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 05 mg / 40 mg (Pack size:100s) (Consists of 168 Kgs of Benazepril Hydrochloride USP	1 Number	6	Benazepril Hydrochloride USP	40.8 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 10 mg / 20 mg (Pack size:100s) (Consists of 168 Kgs of Benazepril Hydrochloride USP	1 Number	7	Benazepril Hydrochloride USP	20.4 mg
Amlodipine and Benazepril Hydrochloride Capsules USP 10 mg / 20 mg (Pack size:500s) (Consists of 28 Kgs of Benazepril Hydrochloride USP	1 Number	8	Benazepril Hydrochloride USP	20.4 mg.
Amlodipine and Benazepril Hydrochloride Capsules USP 10 mg / 40 mg (Pack size:100s) (Consists of 336 Kgs of Benazepril Hydrochloride USP	1 Number	9	Benazepril Hydrochloride USP	40.8 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	102 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025

and Date	
HQ File Number	HQRNORM APPLY 00000133AM26
RA File Number	09AX04001145 AM25
Licence No and Date	0911009401/08/04/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	103 / NC/3/MEET/Dec/202526/11			
Case Status	Case Approved			
Party Name	PIRAMAL PHARMA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025			
HQ File Number	HQRNORM APPLY 00000143AM26			
RA File Number	03AX04000078 AM26			
Licence No and Date	0311042932/08/04/2025			
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:-				

Case No.	104 / NC/3/MEET/Dec/202526/11			
Case Status	Case Approved			
Party Name	PIRAMAL PHARMA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025			
HQ File Number	HQRNORM APPLY 00000144AM26			

RA File Number	03AX04000076 AM26													
Licence No and Date	0311042933/08/04/2025													
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>Vibegron (Gemtesa)Tablets 75 mg</td> <td>1 Number</td> <td>1</td> <td>Vibegron</td> <td>76.50 mg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Vibegron (Gemtesa)Tablets 75 mg	1 Number	1	Vibegron	76.50 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Vibegron (Gemtesa)Tablets 75 mg	1 Number	1	Vibegron	76.50 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	105 / NC/3/MEET/Dec/202526/11													
Case Status	Case Approved													
Party Name	PIRAMAL PHARMA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025													
HQ File Number	HQRNORM APPLY 00000145AM26													
RA File Number	03AX04000077 AM26													
Licence No and Date	0311042934/08/04/2025													
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>Vibegron (Gemtesa)Tablets 75 mg</td> <td>1 Number</td> <td>1</td> <td>Vibegron</td> <td>76.50 mg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Vibegron (Gemtesa)Tablets 75 mg	1 Number	1	Vibegron	76.50 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Vibegron (Gemtesa)Tablets 75 mg	1 Number	1	Vibegron	76.50 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	106 / NC/3/MEET/Dec/202526/11															
Case Status	Case Approved															
Party Name	MAKCUR LABORATORIES LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025															
HQ File Number	HQRNORM APPLY 00000151AM26															
RA File Number	08AX04000031 AM26															
Licence No and Date	0811014671/08/04/2025															
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>Ceftriaxone and Sulbactam for Injection 1.5 gm</td><td>1 Number</td><td>1</td><td>Ceftriaxone Sodium Sterile USP</td><td>1.16 gm.</td></tr><tr><td>Ceftriaxone and Sulbactam for Injection 1.5 gm</td><td>1 Number</td><td>2</td><td>Ceftriaxone Sodium Sterile USP</td><td>1.16 gm.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ceftriaxone and Sulbactam for Injection 1.5 gm	1 Number	1	Ceftriaxone Sodium Sterile USP	1.16 gm.	Ceftriaxone and Sulbactam for Injection 1.5 gm	1 Number	2	Ceftriaxone Sodium Sterile USP	1.16 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Ceftriaxone and Sulbactam for Injection 1.5 gm	1 Number	1	Ceftriaxone Sodium Sterile USP	1.16 gm.												
Ceftriaxone and Sulbactam for Injection 1.5 gm	1 Number	2	Ceftriaxone Sodium Sterile USP	1.16 gm.												
RA concerned may take further necessary action as per above decision of NC.																

Case No.	107 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000158AM26
RA File Number	03AX04000099 AM26
Licence No and Date	0311042949/09/04/2025
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No. 0811013104 dated 29/10/2024, 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.
Indapamide Tablets BP 2.5 mg, Each Firm Coated Tablet contains 2.5mg (Total 3999990 Tablets) (Net Content Bulk Drug Indapamide EP 10.00 kgs))	1 Number	1	Indapamide EP	2.55 mg/Tablet

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

Case No.	108 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000166AM26
RA File Number	09AX04001144 AM25
Licence No and Date	0911009404/09/04/2025

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.
Sulindac	1 kg.	1	4-Fluoro Benzaldehyde	3.18 kg.
		2	Propionic Anhydride	3.15 kg.

		3	Sodium Propionate	2.32 kg.
		4	Methanol	3.14 kg.
		5	Acetic acid	5.71 kg.
		6	Cyano Acetic acid	1.16 kg.

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

Case No.	109 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000171AM26
RA File Number	07AX04000046 AM26
Licence No and Date	0711014148/09/04/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Jul/202526/6 dated 31/07/2025 against advance authorization No. 0711013156 dated 26/12/2024, 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.
Premix of Nifuroxazide (1 gm of Premix contains 0.552 gm of Nifuroxazide)	6300 kg.	1	Nifuroxazide BP/EP	3512.376 kg.

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

Case No.	110 / NC/3/MEET/Dec/202526/11													
Case Status	Case Approved													
Party Name	HONOUR LAB LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025													
HQ File Number	HQRNORM APPLY 00000173AM26													
RA File Number	09AX04001119 AM25													
Licence No and Date	0911009407/09/04/2025													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Umifenovir Hydrochloride (Diloxanide furoate, Cimetidine, Oxytocanide)</td><td rowspan="2">1 kg.</td><td>1</td><td>Ethyl 5-acetoxy-6-bromo-2-(bromomethyl)-1-methyl-1H-indole-3-carboxylate</td><td>1.910 kg.</td></tr><tr><td>2</td><td>Thiophenol</td><td>0.612 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Umifenovir Hydrochloride (Diloxanide furoate, Cimetidine, Oxytocanide)	1 kg.	1	Ethyl 5-acetoxy-6-bromo-2-(bromomethyl)-1-methyl-1H-indole-3-carboxylate	1.910 kg.	2	Thiophenol	0.612 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Umifenovir Hydrochloride (Diloxanide furoate, Cimetidine, Oxytocanide)	1 kg.	1	Ethyl 5-acetoxy-6-bromo-2-(bromomethyl)-1-methyl-1H-indole-3-carboxylate	1.910 kg.										
		2	Thiophenol	0.612 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	111 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000174AM26
RA File Number	09AX04001120 AM25
Licence No and Date	0911009408/09/04/2025
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.
Ticagrelor (Diloxanide furoate, Cimetidine, Oxylozanide)	1 kg.	1	4,6-dichloro-2-(propylsulfanyl)-5-pyrimidiamine (Heterocyclic compounds with nitrogen hetero-atom(s) only)	0.70 kg.
		2	2-(((3aR,4S,6R,6aS)-6-amino-2,2-dimethyltetrahydro-3aH-cyclopenta [d][1,3]dioxol-4-yl)oxy)-1-ethanol L-tartaric acid salt	1.07 kg.
		3	(1R,2S)-2-(3,4-difluorophenyl) cyclopropan-1-amine hydrochloride (Amine- function compounds)	0.58 kg.

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

Case No.	112 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	LEE PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000186AM26
RA File Number	09AX04001209 AM25
Licence No and Date	0911009410/09/04/2025

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.
7,8,9,10-Tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]benzazepine	1 kg.	1	2,3,4,5-Tetrahydro-3-(trifluoroacetyl)-1,5-methano-1H-3-benzazepine	3.85 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	113 / NC/3/MEET/Dec/202526/11													
Case Status	Case Approved													
Party Name	LEE PHARMA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025													
HQ File Number	HQRNORM APPLY 00000187AM26													
RA File Number	09AX04001208 AM25													
Licence No and Date	0911009411/09/04/2025													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>7,8,9,10-Tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]benzazepine</td><td>1 kg.</td><td>1</td><td>2,3,4,5-Tetrahydro-3-(trifluoroacetyl)-1,5-methano-1H-3-benzazepine</td><td>3.85 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	7,8,9,10-Tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]benzazepine	1 kg.	1	2,3,4,5-Tetrahydro-3-(trifluoroacetyl)-1,5-methano-1H-3-benzazepine	3.85 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
7,8,9,10-Tetrahydro-6,10-methano-6H-pyrazino[2,3-h][3]benzazepine	1 kg.	1	2,3,4,5-Tetrahydro-3-(trifluoroacetyl)-1,5-methano-1H-3-benzazepine	3.85 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	114 / NC/3/MEET/Dec/202526/11
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Case Status	Case Approved										
Party Name	DR.REDDY'S LABORATORIES LTD										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025										
HQ File Number	HQRNORM APPLY 00000210AM26										
RA File Number	09AX04001188 AM25										
Licence No and Date	0911009414/11/04/2025										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Sep/202526/8 dated 17/09/2025 against advance authorization No. 0911008287 dated 29/10/2024, 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>Diluted Everolimus 5%</td><td>1 kg.</td><td>1</td><td>Everolimus (Spec-1)</td><td>0.051 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Diluted Everolimus 5%	1 kg.	1	Everolimus (Spec-1)	0.051 kg.
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.	115 / NC/3/MEET/Dec/202526/11			
Case Status	Case Approved			
Party Name	BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025			
HQ File Number	HQRNORM APPLY 00000215AM26			
RA File Number	03AX04000098 AM26			
Licence No and Date	0311043017/12/04/2025			
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:-				

Azithromycin tablets 500MG, (TOTAL 199998 TABLETS) (Net Content Bulk Drug Azithromycin Monohydrate 100 Kgs)	100 kg.	1	Azithromycin Monohydrate	102 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	116 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000225AM26
RA File Number	03AX04000146 AM26
Licence No and Date	0311043033/15/04/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jul/202526/6 dated 31/07/2025 against advance authorization No. 0311041469 dated 18/02/2025 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TYLODOX GOLD WSP (Pack size 1 Kgs Jar) (Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)	1 Number	1	Tylosin Tartrate BP/USP /EP	0.101 kg.
		3	Doxycycline Hyclate BP/EP/USP	0.202 kg.
TYLODOX GOLD WSP (Pack size 100 Gms sachet) (Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)	1 Number	2	Tylosin Tartrate BP/USP /EP	10.1 gm.
		4	Doxycycline Hyclate BP/EP/USP	20.2 gm.

GENTADOX GOLD 100 / 200 (pack Size 1 Kgs Jar) (Each gram powder contains: Doxycycline Hyclate BP 200 mg, Gentamycin Sulphate USP 100 mg)	1 Number	5	Doxycycline Hyclate BP/EP/USP	0.202 kg.
GENTADOX GOLD 100 /200 (pack Size 100 Gms Sachet) (Each gram powder contains: Doxycycline Hyclate BP 200 mg, Gentamycin Sulphate USP 100 mg)	1 Number	6	Doxycycline Hyclate BP/EP/USP	20.2 gm.
NEODOX GOLD WSP (pack Size 1 Kgs Jar)(Each gram contains: Doxycycline Hyclate BP 100 mg Neomycin Sulfate BP 100 mg)	1 Number	7	Doxycycline Hyclate BP/EP/USP	0.101 kg.
NEODOX -GOLD WSP (pack Size 100 Gms Sachet) (Each gram contains: Doxycycline Hyclate BP 100 mg Neomycin Sulfate BP 100 mg)	1 Number	8	Doxycycline Hyclate BP/EP/USP	10.1 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	117 / NC/3/MEET/Dec/202526/11			
Case Status	Case Approved			
Party Name	HONOUR LAB LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025			
HQ File Number	HQRNORM APPLY 00000226AM26			
RA File Number	09AX04001211 AM25			
Licence No and Date	0911009422/15/04/2025			
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:-				

Ethyl-(2R,4S)-5-([1,1-biphenyl]-4-yl)-4-amino-2-methylpentanoate hydrochloride	1 kg.	1	(2R,4S)-5-([1,1-biphenyl]-4-yl)-4-((tert-butoxycarbonyl) amino)-2-methylpentanoic acid	1.21 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	118 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000228AM26
RA File Number	03AX04000116 AM26
Licence No and Date	0311043050/15/04/2025
Norms Committee Decision: The firm was granted an Advance Authorisation for the export product “HEXYL SALICYLATE” 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.	119 / NC/3/MEET/Dec/202526/11										
Case Status	Case Approved										
Party Name	DECCAN NUTRACEUTICALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025										
HQ File Number	HQRNORM APPLY 00000231AM26										
RA File Number	02AX04000021 AM26										
Licence No and Date	0211008522/15/04/2025										
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>Naltrexone Hydrochloride USP/PH.EUR</td><td>1 kg.</td><td>1</td><td>Noroxymorphone Base</td><td>1.03 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.	Naltrexone Hydrochloride USP/PH.EUR	1 kg.	1	Noroxymorphone Base	1.03 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Naltrexone Hydrochloride USP/PH.EUR	1 kg.	1	Noroxymorphone Base	1.03 kg.							

Case No.	120 / NC/3/MEET/Dec/202526/11					
Case Status	Case Approved					
Party Name	JUBILANT GENERICS LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025					
HQ File Number	HQRNORM APPLY 00000235AM26					
RA File Number	05AX04000079 AM26					
Licence No and Date	0511031904/15/04/2025					
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.		

Prochlorperazine Maleate Tablets USP 5mg	1 Number	1	Prochlorperazine Maleate USP	5.10 mg/Tablet
Prochlorperazine Maleate Tablets USP 10mg	1 Number	2	Prochlorperazine Maleate USP	10.20 mg./Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	121 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000244AM26
RA File Number	08AX04000041 AM26
Licence No and Date	0811014718/15/04/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	122 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	JUBILANT GENERICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000246AM26
RA File Number	05AX04000096 AM26
Licence No and Date	0511031914/16/04/2025
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.
Terazosin Capsules USP 1mg ((Net Content of Terazosin Hydrochloride Anhydrous 1 mg to be utilized 9.1 kgs))	1 Number	1	Terazosin Hydrochloride Anhydrous	1.116 mg.
Terazosin Capsules USP 2 mg ((Net Content of Terazosin Hydrochloride Anhydrous 2 mg to be utilized 19 kgs))	1 Number	2	Terazosin Hydrochloride Anhydrous	2.232 mg.
Terazosin Capsules USP 5 mg ((Net Content of Terazosin Hydrochloride Anhydrous 5 mg to be utilized 47.5 kgs))	1 Number	3	Terazosin Hydrochloride Anhydrous	5.581 mg.
Terazosin Capsules USP 10 mg ((Net Content of Terazosin Hydrochloride Anhydrous 10 mg to be utilized 86 kgs))	1 Number	4	Terazosin Hydrochloride Anhydrous	11.16 mg.

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

Case No.	123 / NC/3/MEET/Dec/202526/11			
Case Status	Case Approved			
Party Name	SRF LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025			
HQ File Number	HQRNORM APPLY 00000277AM26			
RA File Number	05AX04004156 AM25			
Licence No and Date	0511031944/16/04/2025			
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:-				

		No.		allowed.
2-BROMO-5- FLUOROBENZOTRIFLUORIDE (BFBTF)	1 kg.	1	3-AMINOBENZOTRIFLUORIDE	0.880 kg.
		2	LIQUID BROMINE	0.445 kg.

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

Case No.	124 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000280AM26
RA File Number	34AX04001073 AM25
Licence No and Date	3411006226/16/04/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	125 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	NATURAL AND ESSENTIAL OILS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000320AM26
RA File Number	07AX04000087 AM26
Licence No and Date	0711014206/17/04/2025
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
1. Complete Certificate of Analysis (CoA) of import item from foreign supplier.	

2. Certificate of Analysis of all export items indicating percentage active content.
3. Percentage wastage claimed.
4. Details of by-product obtained with commercial value.

Complete material balance between import and export.

Case No.	126 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000322AM26
RA File Number	03AX04000224 AM26
Licence No and Date	0311043154/18/04/2025

Norms Committee Decision:

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

Sl. No.	Export Product	Quantity
1	Medical Ointment & cream ("Hydrocortisone 1 Percentage OTC Cream1 OZ/28 gm Tube (Tot Wt:840 Kg Net Cont: (In KGs) Hydro:8.40, Glyceryl 16.80,Wax 25.20, Stearyl 8.40, Isopropyl 67.20, Cety 25.20, Sorbitan 25.20, Polysorb 25.20, Anhydrous 0.59, Sodium 1.01, Sorbic 0.42, polyoxyl 4.2))	1 Number
2	Medical Ointment & cream (Hydrocortisone 1 Percentage OTC Ointment 1 OZ/ 28 gm Tube Tot Wt 4840.02 Kgs Net Cont: (In Kgs) Hydrocortisone USP (Micronized) 48.40Kgs))	1 Number
3	Medical Ointment & cream (Hydrocortisone Aloe 1% Cream 1 OZ/28 gm Tube (Tot Wt 1540Kgs Nt Cont (InKG) Hydrocort 15.40 Glyceryl Stearate 30.80 White wax 46.20 Stearyl 115.40 Isopropyl 123.20 Cetyl 46.20 Sorbitan 46.20 Polysorb 46.20 Anhydrous 1.08 Sodium 1.85 sorbic acid 0.77 Polyoxyl 7.70 Aloe 1.54))	1 Number
4	Medical Ointment & cream (Hydrocortisone Aloe 1% Cream 1 OZ/28 gm Tube (Tot Wt 1540 Kgs Nt Cont (In KG) Hydrocort 15.40 Glyceryl Stearate 30.80 White wax 46.20 Stearyl 115.40 Isopropyl 123.20 Cetyl 46.20 Sorbitan 46.20 Polysorb 46.20 Anhydrous 1.08 Sodium 1.85 sorbic acid 0.77 Polyoxyl 7.70 Aloe 1.54))	1 Number

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

Note:

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

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

Case No.	127 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000332AM26
RA File Number	09AX04000048 AM26
Licence No and Date	0911009467/19/04/2025

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.
Imipenem 500 mg + Relebactam 250 mg + Cilastatin 500 mg powder	1 Number Vial	1	Relebactam monohydrate	276.15 mg.

for the preparation of solution for infusion				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	128 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000340AM26
RA File Number	05AX04000084 AM26
Licence No and Date	0511031988/21/04/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/May/202526/3 dated 04/06/2025 against advance authorization No. 0511028223 dated 10/10/2024, 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.
Brinzolamide Ophthalmic Suspension, 1% w/v 5 ml (Sterile Eye Drops) ((Each ml contains Brinzolamide 10 mg (Equivalent to 1150.000 Gm of Bulk Drug))	1 Number	1	Brinzolamide (Micronized and Sterile)	51.00 mg/Vial
Brinzolamide Ophthalmic Suspension, 1% w/v 10 ml (Sterile Eye Drops) ((Each ml contains Brinzolamide 10 mg (Equivalent to 1500.000 Gm	1 Number	2	Brinzolamide (Micronized and Sterile)	102.00 mg/Vial

of Bulk Drug))				
Brinzolamide Ophthalmic Suspension, 1% w/v 15 ml (Sterile Eye Drops)(Each ml contains Brinzolamide 10 mg (Equivalent to 2250.000 Gm of Bulk Drug) (Total 4900.000 Gm of Bulk Drug)	1 Number	3	Brinzolamide (Micronized and Sterile)	153.00 mg/Vial

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

Case No.	129 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000345AM26
RA File Number	05AX04000073 AM26
Licence No and Date	0511031999/21/04/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Jun/202526/5 dated 30/06/2025 against advance authorization No. 0511029128 dated 22/11/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tobramycin 300 mg / 5 ml Nebuliser Solution ((Each ml contains Tobramycin Ph. Eur. 60 mg) (Equivalent to 572.880 Kg of Bulk Drug))	1 Number Pack	1	Tobramycin	315 mg/Vial

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

NC also recommended for making a new SION for this export product.

Case No.	130 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000373AM26
RA File Number	03AX04000242 AM26
Licence No and Date	0311043189/22/04/2025

Norms Committee Decision:

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

Sl. No.	Export Product	Quantity
1	Medical Ointment & Cream ("Fluorouracil Topical Solution USP 5%, 10 ml Total Nt Wt. 250 Kgs (fluor 12.5 Kgs, ede 0.13kgs, met 0.25, gly 119.76, para 0.08 Kgs, tro 21 kgs, hyd 6.25 kg, bot 25000, drop 25000, cap 25000)")	1 Number
2	Medical Ointment & Cream (Fluorouracil Cream USP 5% 40 Gm Total Nt Wt. 7200 Kgs (fluor 360 Kgs, wh petro 1512 kgs, progly 864Kgs, stearyl alco 1080, poly 288 Kgs, pro para 1.08 kgs, methyl 1.8 Kgs))	1 Number

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

Note:

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

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

Case No.	131 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000379AM26
RA File Number	07AX04000114 AM26
Licence No and Date	0711014238/22/04/2025
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete chemical reaction, indicating molecular weight of reactant/s and product/s with overall yield of the reaction for both the export items. 2. Production specifically for both the export items vis-à-vis consumption of raw materials for the last three years duly certified by Chartered Accountant. 3. Copy of minutes of norms committee, if, approved in the past.	

Case No.	132 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000384AM26
RA File Number	07AX04000107 AM26
Licence No and Date	0711014246/22/04/2025
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No. 0711012278 dated 06/09/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dexamethasone Sodium Phosphate 1 ml. Injection (Net Contents 3334 kg))	1 Number	1	Dexamethasone Sodium Phosphate USP	11.76 mg/Vial

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

Case No.	133 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000388AM26
RA File Number	07AX04000121 AM26
Licence No and Date	0711014253/22/04/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Sep/202526/8 dated 17/09/2025 against advance authorization No. 0711013517 dated 30/01/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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.	134 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000389AM26
RA File Number	07AX04000106 AM26
Licence No and Date	0711014254/22/04/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Oct/202526/9 dated 14/10/2025 against advance authorization No. 0511031098 dated 27/02/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Losartan Potassium 25 mg. Tablets	1 Number	1	Losartan Potassium (BP/EP/USP/IP)	25.50 mg.

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

Case No.	135 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000409AM26
RA File Number	08AX04000104 AM26

Licence No and Date	0811014779/23/04/2025			
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 in 0.7% Sodium Chloride Injection 1,000 mg. per 100 mL (10 mg / mL)	Number	1	Tranexamic acid (Injectable grade, US FDA approved	1050 mg. /100 ml. Vial
RA concerned may take further necessary action as per above decision of NC.				

Case No.	136 / NC/3/MEET/Dec/202526/11
Case Status	Case Rejected
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000425AM26
RA File Number	05AX04000229 AM26
Licence No and Date	0511032095/24/04/2025
Norms Committee Decision:	
The firm was granted an Advance Authorisation for the export product “Massoia Lactone” 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.	137 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000437AM26
RA File Number	09AX04000044 AM26
Licence No and Date	0911009506/24/04/2025

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.
Teriparatide Injection 560 mcg / 2.24 ml. (Each ml. contains Teriparatide - 250 mcg)	1 Number	1	Teriparatide ((Parathyroid Hormone (1-34) Human, Acetate))	616.0 mcg/Vial

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

Case No.	138 / NC/3/MEET/Dec/202526/11
Case Status	Case Approved
Party Name	WINDLAS BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025

HQ File Number	HQRNORM APPLY 00000441AM26										
RA File Number	05AX04000217 AM26										
Licence No and Date	0511032119/24/04/2025										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Moxifloxacin Tablet 400 mg Pack Size 30 tablet in a bottle (Total 3,30,000 tablets in 11000 bottles)</td><td>1 Number Tablet</td><td>1</td><td>Moxifloxacin HCL</td><td>408.0 mg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Moxifloxacin Tablet 400 mg Pack Size 30 tablet in a bottle (Total 3,30,000 tablets in 11000 bottles)	1 Number Tablet	1	Moxifloxacin HCL	408.0 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Moxifloxacin Tablet 400 mg Pack Size 30 tablet in a bottle (Total 3,30,000 tablets in 11000 bottles)	1 Number Tablet	1	Moxifloxacin HCL	408.0 mg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	139 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025
HQ File Number	HQRNORM APPLY 00000460AM26
RA File Number	07AX04000137 AM26
Licence No and Date	0711014284/25/04/2025
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	140 / NC/3/MEET/Dec/202526/11
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202526/ 11 and 18/12/2025

HQ File Number	HQRNORM APPLY 00000461AM26
RA File Number	07AX04000136 AM26
Licence No and Date	0711014285/25/04/2025
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	