



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Nov/202526/10

DATED: 14/11/2025

Minutes of the Norms Committee–3 Meeting No.NC/3/MEET/Nov/202526/10 dated 14/11/2025 under the Chairmanship of Shri Rakesh Kumar, Addl. DGFT for considering the cases/issues under Duty Exemption Scheme (Chapter-4) of the Foreign Trade Policy, 2023 pertaining to Chemical and Allied products falling under Chapter 29 and 30.

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

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

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.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	Raman Kumar, Deputy DGFT	DGFT(HQ)
2	Skina Rani, FTDO	DGFT(HQ)
3	Dineshnarain Mathur, Technical Consultant	DGFT
4	Nand Lal, Technical Consultant	DGFT
5	Shaish Kumar, Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	FARMSON BASIC DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00001438AM26
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: Decision: The committee considered the case as per agenda and it has been observed that there is no technical details, Drug Manufacturing Licence (DML) or any other relevant documents in support of import items and their requirement. Hence, it was decided that RA may decide the norm as per SION A-344.	

Case No.	2 / NC/3/MEET/Nov/202526/10																
Case Status	Case Approved																
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025																
HQ File Number	HQRNORM APPLY 00002836AM26																
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 to enable them to obtain Advance Authorization from concerned RA and it was decided to fix ad-hoc norms 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">Fenofibrate 48 mg tablets) (7,000,000 NOS) (Net Content:1) Fenofibrate Micronized IH/Ph Eur: 336.00 KGS 2) Sucrose PH.Euro: 341.194.00 KGS)</td><td rowspan="2">1 Number</td><td>1</td><td>Fenofibrate Micronized IH/Ph Eur</td><td>48.96 mg.</td></tr><tr><td>2</td><td>Sucrose PH.Euro</td><td>145.57 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Fenofibrate 48 mg tablets) (7,000,000 NOS) (Net Content:1) Fenofibrate Micronized IH/Ph Eur: 336.00 KGS 2) Sucrose PH.Euro: 341.194.00 KGS)	1 Number	1	Fenofibrate Micronized IH/Ph Eur	48.96 mg.	2	Sucrose PH.Euro	145.57 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Fenofibrate 48 mg tablets) (7,000,000 NOS) (Net Content:1) Fenofibrate Micronized IH/Ph Eur: 336.00 KGS 2) Sucrose PH.Euro: 341.194.00 KGS)	1 Number	1	Fenofibrate Micronized IH/Ph Eur	48.96 mg.													
		2	Sucrose PH.Euro	145.57 mg.													

Fenofibrate 145 mg tablets) (101015000 Nos) (Net Content:3) Fenofibrate Micronized IH/Ph Eur: 14647.175 KG S 4) Sucrose PH.Euro: 14873.449 KGS)	1 Number	3	Fenofibrate Micronized	147.90 mg.
		4	Sucrose PH.Euro	146.45 mg.
Fenofibrate Bulk Granulate (Net Content: 5) Fenofibrate Micronized IH/Ph.Eur: 2099.4048 KG S 6) Sucrose Ph.Eur : 2069.376 KGS)	1 Kg.	5	Fenofibrate Micronized	0.3155 kg.
		6	Sucrose Ph.Eur	0.3124 kg.

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

Case No.	3 / NC/3/MEET/Nov/202526/10			
Case Status	Case Approved			
Party Name	ZYDUS LIFESCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025			
HQ File Number	HQRNORM APPLY 00003316AM26			
RA File Number	NA			
Licence No and Date	NA			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202324/26 dated 22/03/2024 against DGFT (Hqr.) File No. HQRNORMAPPLY00008565AM24, 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.
MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 7 MG ((ACTIVE PHARMACEUTICAL	1 Number	1	MEMANTINE HYDROCHLORIDE USP	7.14 mg.
		2	SUGAR SPHERES (NON-PAREIL) NF	30.60 mg.

INGREDIENT: MEMANTINE HYDROCHLORIDE USP))		3	HYPROMELLOSE 5 CPS 2910 USP	3.824 mg.
		4	HYPROMELLOSE 3 CPS 2910 USP	3.06 mg.
		5	TRIETHYL CITRATE NF	0.829 mg.
		6	TALC PH EUR/USP	1.594 mg.
MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 14 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))	1 Number	7	MEMANTINE HYDROCHLORIDE USP	14.28 mg.
		8	SUGAR SPHERES (NON-PAREIL) NF	61.20 mg.
		9	HYPROMELLOSE 5 CPS 2910 USP	7.648 mg.
		10	HYPROMELLOSE 3 CPS 2910 USP	6.12 mg.
		11	TRIETHYL CITRATE NF	1.658 mg.
		12	TALC PH EUR/USP	3.188 mg.
MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 21 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))	1 Number	13	MEMANTINE HYDROCHLORIDE USP	21.42 mg.
		14	SUGAR SPHERES (NON-PAREIL) NF	91.80 mg.
		15	HYPROMELLOSE 5 CPS 2910 USP	11.472 mg.
		16	HYPROMELLOSE 3 CPS 2910 USP	9.18 mg.
		17	TRIETHYL CITRATE NF	2.487 mg.
		18	TALC PH EUR/USP	4.782 mg.
MEMANTINE HYDROCHLORIDE EXTENDED	1 Number	19	MEMANTINE HYDROCHLORIDE USP	28.56 mg.

RELEASE CAPSULES 28 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))		20	SUGAR SPHERES (NON-PAREIL) NF	122.40 mg.
		21	HYPROMELLOSE 5 CPS 2910 USP	15.296 mg.
		22	HYPROMELLOSE 3 CPS 2910 USP	12.24 mg.
		23	TRIETHYL CITRATE NF	3.316 mg.
		24	TALC PH EUR/USP	6.376 mg.
MEMANTINE HYDROCHLORIDE TABLETS 5 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))	1 Number	25	MEMANTINE HYDROCHLORIDE USP	5.10 mg.
		26	TALC PH EUR/USP	1.02 mg.
		27	CROSCARMELLOSE SODIUM NF	5.61 mg.
		28	DIBASIC CALCIUM PHOSPHATE DIHYDRATE USP	73.95 mg.
		29	MAGNESIUM STEARATE PH.E/NF/JP	1.02 mg.
MEMANTINE HYDROCHLORIDE TABLETS 10 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))	1 Number	30	MEMANTINE HYDROCHLORIDE USP	10.20 mg.
		31	TALC PH EUR/USP	2.04 mg.
		32	CROSCARMELLOSE SODIUM NF	11.22 mg.
		33	DIBASIC CALCIUM PHOSPHATE DIHYDRATE USP	147.90 mg.
		34	MAGNESIUM STEARATE PH.E/NF/JP	2.04 mg.

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

Case No.	4 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	PRIVI FINE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003704AM26
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 to enable them to obtain Advance Authorization from concerned RA and it was decided to fix ad-hoc norms as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cyclamen Aldehyde	1 kg.	1	Cuminaldehyde	0.916 kg.
		2	Propionnaldehyde	0.360 kg.

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

Case No.	5 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00004088AM26
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 that a potency correction exceeding 8% has been claimed in the norm calculation.

Accordingly, it was decided to call the firm for a Personal Hearing before the Norms Committee to justify the claim and submit relevant supporting documents/information.

Case No.	6 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	HALEOS LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005583AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The Committee considered the firm's request for a review of the ad-hoc norms. Upon examination, it was observed that the firm had not furnished any substantive technical justification or supporting information to warrant an enhancement of the existing norms. In the absence of any new material evidence or justification, the Committee found no reasonable grounds to review or revise the norms. Accordingly, it was decided to reject the request and maintain the status quo.	

Case No.	7 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	WEXFORD LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00003783AM25
RA File Number	072404000382 AM14
Licence No and Date	0710101548/23/01/2014
Norms Committee Decision:	
The firm was called for Personal Hearing on 19/11/2025 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.	8 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	GLOBE TROTTERS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00004519AM25
RA File Number	039404000124 AM16
Licence No and Date	0310796194/26/05/2015
Norms Committee Decision: The representative of the firm appeared for the Personal Hearing and explained their case. During the hearing, they sought additional input items beyond those originally declared and admitted to the same in the meeting. This constitutes a case of misdeclaration. Accordingly, the Norms Committee advised the Regional Authority to initiate action against the firm under the FTDR Act for such misdeclaration. The Committee also directed the firm to submit copies of the Bills of Entry pertaining to their imports. The norms will be finalised based on the firm's reply and the documents submitted.	

Case No.	9 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00000262AM24
RA File Number	039404000295 AM18
Licence No and Date	0310814908/31/07/2017
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	10 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	WEXFORD LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00003782AM25

RA File Number	072404000120 AM18
Licence No and Date	0710111992/09/08/2017
Norms Committee Decision: The firm was called for Personal Hearing on 19/11/2025 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.	11 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	GLOBE TROTTERS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00004505AM25
RA File Number	039404000713 AM19
Licence No and Date	0310825212/26/11/2018
Norms Committee Decision: The representative of the firm appeared for the Personal Hearing and explained their case. During the hearing, they sought additional input items beyond those originally declared and admitted to the same in the meeting. This constitutes a case of misdeclaration. Accordingly, the Norms Committee advised the Regional Authority to initiate action against the firm under the FTDR Act for such misdeclaration. The Committee also directed the firm to submit copies of the Bills of Entry pertaining to their imports. The norms will be finalized based on the firm's reply and the documents submitted.	

Case No.	12 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	018205000499AM20
RA File Number	039404000373 AM20
Licence No and Date	0310830887/07/08/2019
Norms Committee Decision:	

The firm was called for Personal Hearing on 19/11/2025 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for Personal Hearing with relevant documents/information.

Case No.	13 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00000048AM25
RA File Number	318304000087 AM20
Licence No and Date	3110067548/30/09/2019
Norms Committee Decision:	
The Committee considered the request of firm for fixation of ad-hoc norms and it has been observed that the firm vide e-mail dated 16/09/2025 has informed that they have withdraw the application from RA and requested to withdrawa the application from portal. Therefore, it was decided to close the application of the firm.	

Case No.	14 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005226AM25
RA File Number	052404000616 AM20
Licence No and Date	0510413195/03/01/2020
Norms Committee Decision:	
The firm was initially granted an Advance Authorisation for the export product “<i>Sclareolide</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.	15 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00006406AM25
RA File Number	082404000394 AM20
Licence No and Date	0810147815/22/05/2020
Norms Committee Decision:	
The Committee considered the firm's request for a review of the ad-hoc norms and it has been observed that Certificate of Analysis (CoA) submitted by the firm refers to 2016-17 whereas Advance Authorisation is of 2022-21. Therefore, it was decided to call the following documents from the firm: 1. Revised Certificate of Analysis (CoA) of import item relevant to present Advance Authorisation. 2. Revised Production/consumption data duly certified by CA for the last three years.	

Case No.	16 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00003807AM25
RA File Number	039404000166 AM21
Licence No and Date	0310836755/19/06/2020

Norms Committee Decision:

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

Case No.	17 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	ALKALI METALS LTD.
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005538AM25
RA File Number	09AA04009415 AM22
Licence No and Date	0911001301/03/08/2021
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. Step wise manufacturing process. 2. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. 3. Complete technical details as per Annexure to Appendix-4E for chemical products. 4. Stoichiometric balance between import and export on molar basis.	

Case No.	18 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005553AM25
RA File Number	05AA04070230 AM22
Licence No and Date	0511004557/06/09/2021
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. Statement of actual consumption of imported inputs for present Advance Authorisation and another	

Advance Authorisation No. 0511015715 dated 09.11.2022 certified by company Auditor and justification for any difference in the consumption norms.
2. Percentage recovery of Pentanol achieved now.

Case No.	19 / NC/3/MEET/Nov/202526/10													
Case Status	Case Approved													
Party Name	METROPOLITAN EXIMCHEM PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025													
HQ File Number	HQRNORM REVIW00001611AM26													
RA File Number	03AA040108347 AM22													
Licence No and Date	0311007901/25/10/2021													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>9-ETHYL CARBAZOLE</td><td>1 kg.</td><td>1</td><td>CARBAZOLE</td><td>1.01 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	9-ETHYL CARBAZOLE	1 kg.	1	CARBAZOLE	1.01 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
9-ETHYL CARBAZOLE	1 kg.	1	CARBAZOLE	1.01 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	20 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	LAZERHEAD LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00006211AM25
RA File Number	09AA04012424 AM22
Licence No and Date	0911001950/26/11/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ovaplant 150 mcg (Salmon Gonadotropin Releasing Hormone Analogue Implant)	40000 Numbers	1	Salmon Gonadorelin	6.0 gm.
Ovaplant 250 mcg (Salmon Gonadotropin Releasing Hormone Analogue Implant)	44000 Numbers	2	Salmon Gonadorelin	11.0 gm.

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

Case No.	21 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	PANACEA BIOTEC PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005946AM24
RA File Number	05AX04000321 AM22
Licence No and Date	0511007823/11/01/2022

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.
Paclitaxel (Protein-Bound Particles for Injectable Suspension 100 mg)	100,000 Vials	1	Paclitaxel	102 kg.
		2	Albumin Human USP (25% Solution)	464.4 Litre
		3	Rubber Stopper	1,02000 Numbers

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

Case No.	22 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00006380AM25
RA File Number	03AX04001943 AM23
Licence No and Date	0311016208/08/07/2022
Norms Committee Decision: The Committee considered the case and observed that firm is importing Soda Ash which is under policy restriction. Accordingly Committee is decided to that RA will visit the premises of the factory and check records of use of soda ash and send a report to this committee as well as PC-4.	

Case No.	23 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00004127AM25
RA File Number	03AX04002151 AM23
Licence No and Date	0311016241/11/07/2022
Norms Committee Decision: The firm was called for Personal Hearing on 19/11/2025 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for Personal Hearing with relevant documents/information.	

Case No.	24 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	SRF LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005332AM25
RA File Number	05AX04001011 AM23
Licence No and Date	0511013749/13/07/2022

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.
3-DIFLUOROMETHYL-1-METHYL-1H-PYRAZOLE-4-CARBOXYLIC ACID	1 kg.	1	Dimethyl Formamide	0.950 kg.
		2	Sodium Methoxide Powder	0.670 kg.
		3	Acetonitrile	0.520 kg.
		4	Tri Ethyl Amine (TEA)	0.350 kg.
		5	Toluene	0.315 kg.
		6	Mixed Hexanes	0.236 kg.
		7	N-Butanol	0.010 kg.
		8	Hydrazine Hydrate (100%)	0.4943 kg.
		9	Hydrazine Hydrate (64%)	0.7723 kg.
		10	Jumbo Bag 910 X 910 X 1000 MM	Relevant, as per Packing Policy and General Notes.
		11	Jumbo Bag 920 X 920 X 1200 MM	Relevant, as per Packing Policy and General Notes.
		12	Jumbo Bag 910 X 910 X 900	Relevant, as per

			MM	Packing Policy and General Notes.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	25 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	STERLING AUXILIARIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005178AM25
RA File Number	03AX04002204 AM23
Licence No and Date	0311016388/15/07/2022
Norms Committee Decision:	
The committee considered the request of firm for 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. Percentage active content of each of export item. 2. Specific name of import item 'Escorene, MC1037 and M 19.	

Case No.	26 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	ALIVUS LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003339AM23
RA File Number	03AX04003267 AM23
Licence No and Date	0311018114/24/09/2022
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.
Voriconazole	1 kg.	1	1R-10-Camphor Sulphonic Acid	1.01 kg.
		2	6-Ethyl-5-Fluro-4-Hydroxypyrimidine	3.30 kg.
		3	Acetic Acid Glacial	5.00 kg.
		4	Acetone	1.35 kg.
		5	Ethyl Acetate	6.47 kg.
		6	Iso Propyl Alcohol	1.62 kg.
		7	Methanol	0.74 kg.
		8	Methylene Chloride (MDC)	2.68 kg.
		9	Tetra Hydro Furan (THF)	9.38 kg.
		10	Tri Ethyl Amine	2.00 kg.

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

Case No.	27 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005557AM25
RA File Number	03AX04003155 AM23
Licence No and Date	0311018363/05/10/2022
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 justification:-

1. Silicon Dioxide (SiO₂) already given in the approved norms in line with Drug Manufacturing Licence (DML) for the export product. Why additional quantity of SiO₂ is applied for?

Case No.	28 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	CORAL DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00006318AM25
RA File Number	05AX04001818 AM23
Licence No and Date	0511015160/06/10/2022
Norms Committee Decision: The Committee considered the firm's request for a review of the ad-hoc norms. Upon examination, it was observed that the firm had not furnished any substantive technical justification or supporting information to warrant an enhancement of the existing norms. In the absence of any new material evidence or justification, the Committee found no reasonable grounds to review or revise the norms. Accordingly, it was decided to reject the request and maintain the status quo.	

Case No.	29 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00003221AM25
RA File Number	05AX04002301 AM23
Licence No and Date	0511015737/10/11/2022
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.
Easyfive TT Vaccine DTwP-Hep B-Hib- Pentavalent Vaccine (Each vial of 5.0ml contains 10 dose) with Vaccine Vial Monitor	10,00,000 Vials	1	Diphtheria Toxoid Bulk	99.05 Litre
		2	Tetanus Toxoid Bulk	38.1 Litre
		3	Pertussis Bulk	688.5 Litre
		4	Aluminium Phosphate Gel	636.2 kg.
		5	Electronic Temperature Data Logger	1300 Numbers
		6	Rubber Stopper	10,10,000 Numbers
		7	VVM Dot 14	10,15,000 Numbers
		8	Ags Hb Purification Mabs Column	54 Litre
		9	Tetanus Toxoid for Conjugation	49.2 Litre

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

Case No.	30 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00005825AM23
RA File Number	05AX04003069 AM23
Licence No and Date	0511016941/19/01/2023
Norms Committee Decision:	
The firm was called for Personal Hearing on 19/11/2025 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for Personal	

Hearing with relevant documents/information.

Case No.	31 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	SYNERGIA SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00006312AM23
RA File Number	03AX04005369 AM23
Licence No and Date	0311021429/14/02/2023
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 detailed information that bifurcation in quantity of export made from Alpha Picoline and from (3 Ethanol Pyridine+Butyl Chloroformate).	

Case No.	32 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005335AM25
RA File Number	05AX04003614 AM23
Licence No and Date	0511018112/31/03/2023
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “<i>Ambroxan</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.	33 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00006354AM25
RA File Number	03AX04006341 AM23
Licence No and Date	0311022753/12/04/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	34 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00001916AM26
RA File Number	03AX04000161 AM24
Licence No and Date	0311022971/20/04/2023
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. Complete and balanced chemistry showing molecular weight. 2. Percentage yield on molar basis for each step.	

3. Molar requirement of reactants with technical justification.
4. Justification for the requirement of import item No. 5 and 6.

Case No.	35 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00006080AM25
RA File Number	05AX04000214 AM24
Licence No and Date	0511018497/25/04/2023
Norms Committee Decision: The Committee considered the firm's request for a review of the ad-hoc norms. Upon examination, it was observed that the firm had not furnished any substantive technical justification or supporting information to warrant an enhancement of the existing norms. In the absence of any new material evidence or justification, the Committee found no reasonable grounds to review or revise the norms. Accordingly, it was decided to reject the request and maintain the status quo	

Case No.	36 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	AGRO SOLVENT PRODUCTS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00001107AM24
RA File Number	56AX04000449 AM23
Licence No and Date	5611001909/25/05/2023
Norms Committee Decision: The firm was called for Personal Hearing on 19/11/2025 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.	37 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	CONNEX PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005897AM25
RA File Number	26AX04000033 AM24
Licence No and Date	2611000980/16/06/2023
Norms Committee Decision: The Committee considered the firm's request for a review of the ad-hoc norms. Upon examination, it was observed that the firm had not furnished any substantive technical justification or supporting information to warrant an enhancement of the existing norms. In the absence of any new material evidence or justification, the Committee found no reasonable grounds to review or revise the norms. Accordingly, it was decided to reject the request and maintain the status quo.	

Case No.	38 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00002939AM26
RA File Number	05AX04000851 AM24
Licence No and Date	0511019523/26/06/2023
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Complete chemistry, molecular weight and percentage yield and Stichometric balance on molar basis submitted at the time of application.	

Case No.	39 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025

HQ File Number	HQRNORM REVIW00005259AM25
RA File Number	05AX04001146 AM24
Licence No and Date	0511020026/25/07/2023
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “<i>Ambroxide</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.	40 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	KELVIN NATURAL MINT PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00004732AM24
RA File Number	05AX04001031 AM24
Licence No and Date	0511019800/31/07/2023
Norms Committee Decision: The committee considered the application of the firm and it has been observed that various opportunities were given to firm but the firm has not appeared for personal hearing before committee to explain their case, therefore, the committee decided to reject the application of the firm.	

Case No.	41 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00004957AM24
RA File Number	03AX04002106 AM24
Licence No and Date	0311026174/09/08/2023
Norms Committee Decision: The firm was called for Personal Hearing on 19/11/2025, 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 sample of all import items.	

Case No.	42 / NC/3/MEET/Nov/202526/10																			
Case Status	Case Approved																			
Party Name	HIKAL LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025																			
HQ File Number	HQRNORM APPLY 00004972AM24																			
RA File Number	03AX04002023 AM24																			
Licence No and Date	0311026196/10/08/2023																			
Norms Committee Decision:																				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																				
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td rowspan="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.	43 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	STANEX DRUGS AND CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00005456AM24
RA File Number	09AX04000507 AM24
Licence No and Date	0911005765/05/09/2023
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. Technical Process flow diagram of manufacturing of Heparin Sodium Injection and Wastage involved at each step. 2. Batch manufacturing record and material issued and material reconciliation sheet for production of a batch for Heparin Sodium Injection, duly signed by dealing QA/Executive/Manager. 3. Justification of claiming 46% wastage.	

Case No.	44 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00005822AM24
RA File Number	03AX04002768 AM24
Licence No and Date	0311027333/22/09/2023
Norms Committee Decision: The firm was called for Personal Hearing on 19/11/2025, 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 sample of all import items.	

Case No.	45 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00006355AM25
RA File Number	03AX04002920 AM24
Licence No and Date	0311027458/27/09/2023
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. How many moles of acetaldoxime are used in chemical reaction. 2. Balanced chemical reaction, stichometric balance on molar basis with percentage yield at every stage. 3. Justification of low yield from crude to final product. 4. Certificate of Analysis (CoA) of export item with percentage purity. 5. Current production/consumption data duly certified by CA.	

Case No.	46 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00006171AM25
RA File Number	05AX04002383 AM24
Licence No and Date	0511021940/07/11/2023
Norms Committee Decision: The Committee considered the firm's request for a review of the ad-hoc norms. Upon examination, it was observed that the firm had not furnished any substantive technical justification or supporting information to warrant an enhancement of the existing norms. In the absence of any new material evidence or justification, the Committee found no reasonable grounds to review or revise the norms. Accordingly, it was decided to reject the request and maintain the status quo.	

Case No.	47 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected

Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005245AM25
RA File Number	05AX04002297 AM24
Licence No and Date	0511022013/10/11/2023
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “<i>Ambroxan</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.	48 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00007039AM24
RA File Number	07AX04001335 AM24
Licence No and Date	0711009794/24/11/2023
Norms Committee Decision: The Committee considered the case as per the agenda, and it has been observed that the firm has paid the duty and interest and also closed the licence through the concerned RA. Therefore, it was decided to close the application of the firm.	

Case No.	49 / NC/3/MEET/Nov/202526/10													
Case Status	Case Approved													
Party Name	CHEMPLAST SANMAR LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025													
HQ File Number	HQRNORM APPLY 00007529AM24													
RA File Number	04AX04000830 AM24													
Licence No and Date	0411006605/21/12/2023													
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. 0411007575 dated 13/06/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<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">(4R)-2-oxooxazolidine-4-carboxylic acid (COX)</td><td rowspan="2">1 kg.</td><td>1</td><td>D-Serine ((R)-2-amino-3-hydroxypropanoic acid)</td><td>1.073 kg.</td></tr><tr><td>2</td><td>Potassium methoxide 32% in methanol</td><td>2.240 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	(4R)-2-oxooxazolidine-4-carboxylic acid (COX)	1 kg.	1	D-Serine ((R)-2-amino-3-hydroxypropanoic acid)	1.073 kg.	2	Potassium methoxide 32% in methanol	2.240 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
(4R)-2-oxooxazolidine-4-carboxylic acid (COX)	1 kg.	1	D-Serine ((R)-2-amino-3-hydroxypropanoic acid)	1.073 kg.										
		2	Potassium methoxide 32% in methanol	2.240 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	50 / NC/3/MEET/Nov/202526/10			
Case Status	Case Approved			
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025			
HQ File Number	HQRNORM APPLY 00007557AM24			
RA File Number	08AX04001743 AM24			
Licence No and Date	0811010331/22/12/2023			

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. 0811010589 dated 29/01/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 200 mcg/50 mL (4 mcg/mL)	1 Number	1	Dexmedetomidine Hydrochloride, USP	210.00 mcg.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 400 mcg/100 mL (4 mcg/mL)	1 Number	2	Dexmedetomidine Hydrochloride, USP	420.00 mcg.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 200 mcg per 50 mL (4 mcg/mL)	1 Number	3	Dexmedetomidine Hydrochloride, USP	210.00 mcg.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 400 mcg per 100 mL (4 mcg/mL)	1 Number	4	Dexmedetomidine Hydrochloride, USP	420.00 mcg.

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

Case No.	51 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00008210AM24
RA File Number	05AX04003445 AM24
Licence No and Date	0511023507/30/01/2024
Norms Committee Decision:	

The firm was called for Personal Hearing on 19/11/2025 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for Personal Hearing with relevant documents/information.

Case No.	52 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00008214AM24
RA File Number	34AX04000788 AM24
Licence No and Date	3411004560/30/01/2024

Norms Committee Decision:

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

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

		7	Magnesium Stearate (Vegetable Source)	2.25 mg.
Doxycycline Caps. USP 100 mg	1 Number	8	Doxycycline Monohydrate USP	109.68 mg.
		9	Microcrystalline Cellulose (Avicel PH 301)	118.498 mg.
		10	Sodium Starch Glycolate (Type A) (EXPLOTAB)	17.00 mg.
		11	Povidone (Kollidon30 LP)	8.00 mg.
		12	Microcrystalline Cellulose (Avicel PH 200 LM)	20.00 mg.
		13	Colloidal Silicon Dioxide (Aerosil 200 Pharma)	1.45 mg.
		14	Magnesium Stearate (Vegetable Source)	3.00 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	53 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00008260AM24
RA File Number	03AX04004795 AM24
Licence No and Date	0311030581/31/01/2024
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:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Potassium Chloride ER Tablets USP 10 m Eq (Net content of Potassium Cl. is 17283 kg and of Polyvinyl Acetate is 3456.60 kg)	1 Number	1	Potassium Chloride USP (40-200 CS)	765.00 mg.
		2	Polyvinyl Acetate NF, Kollicoat SR 30D Dispersion USP	150.00 mg.
Potassium Chloride ER Tablets USP 20 mEq (Net content of Potassium Cl. is 234679.50 kg and of Polyvinyl Acetate is 39113.25 kg)	1 Number	3	Potassium Chloride USP (40-200 CS)	1530.00 mg.
		4	Polyvinyl Acetate NF, Kollicoat SR 30D	250.00 mg.

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

Case No.	54 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00008274AM24
RA File Number	05AX04003478 AM24
Licence No and Date	0511023580/01/02/2024

Norms Committee Decision:

The firm was initially granted an Advance Authorisation for the export product “Ambrox/Ambroxide” 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.	55 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	SPC LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00006369AM25
RA File Number	34AX04000824 AM24
Licence No and Date	3411004576/05/02/2024
Norms Committee Decision:	
The Committee reviewed the matter as per the agenda and noted that the firm has still not submitted the reply to the Deficiency Letter as previously requested. Accordingly, the Committee decided to issue a further reminder to the firm to submit the reply without delay.	

Case No.	56 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00008367AM24
RA File Number	52AX04000336 AM24
Licence No and Date	5211007280/06/02/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant information / documents from the	

firm.

Case No.	57 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00006356AM25
RA File Number	03AX04004580 AM24
Licence No and Date	0311031163/14/02/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. How many moles of acetaldoxime are used in chemical reaction? II. Balanced chemical reaction, stichometric balance on molar basis with percentage yield at every stage. III. Justification of low yield from crude to final product. IV. Certificate of Analysis (CoA) of export item with percentage purity. V. Current production/consumption data duly certified by CA.	

Case No.	58 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	SHARP MINT LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00008852AM24
RA File Number	05AX04003809 AM24
Licence No and Date	0511024175/01/03/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Menthol Crystals	1 kg.	1	Menthol Laevo Dist	1.02 kg.

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

Case No.	59 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00008937AM24
RA File Number	09AX04001083 AM24
Licence No and Date	0911006881/06/03/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	60 / NC/3/MEET/Nov/202526/10			
Case Status	Case Approved			
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025			
HQ File Number	HQRNORM APPLY 00008940AM24			
RA File Number	09AX04001061 AM24			
Licence No and Date	0911006884/06/03/2024			
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:-				

N(2(4((4fluorobenzyl)carbamoyl)5hydroxy1methyl6oxo1,6dihydropyrimidin2yl)propan2yl)5methyl1,3,4oxadiazole2carboxamide	1 kg.	1	Dimethyl acetylene dicarboxylate	2.50 kg.
		2	4-Flouro benzyl amine	0.62 kg.
		3	Methanol	7.74 kg.
		4	Acetic acid	3.017 kg.

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

Case No.	61 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00009103AM24
RA File Number	03AX04005671 AM24
Licence No and Date	0311032149/14/03/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with sample of all import items.	

Case No.	62 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	GALAXY SURFACTANTS LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00004387AM25
RA File Number	03AX04006008 AM24
Licence No and Date	0311032549/27/03/2024
Norms Committee Decision:	

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

1. Certificate of Analysis (CoA) report of export item indicating active content.
2. How the product is different from the export item indicated at SION No. A-3574.

Case No.	63 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005650AM25
RA File Number	03AX04000029 AM25
Licence No and Date	0311032850/05/04/2024
Norms Committee Decision:	
The Committee considered the firm's request for a review of the ad-hoc norms. Upon examination, it was observed that the firm had not furnished any substantive technical justification or supporting information to warrant an enhancement of the existing norms. In the absence of any new material evidence or justification, the Committee found no reasonable grounds to review or revise the norms. Accordingly, it was decided to reject the request and maintain the status quo.	

Case No.	64 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00004138AM25
RA File Number	03AX04000426 AM25
Licence No and Date	0311033410/29/04/2024
Norms Committee Decision:	
The Committee considered the firm's request for a review of the ad-hoc norms. Upon examination, it was observed that the firm had not furnished any substantive technical justification or supporting information to warrant an enhancement of the existing norms. In the absence of any new material evidence or justification,	

the Committee found no reasonable grounds to review or revise the norms. Accordingly, it was decided to reject the request and maintain the status quo.

Case No.	65 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00000484AM25
RA File Number	09AX04001160 AM24
Licence No and Date	0911007159/30/04/2024

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. Function/application of import chemicals which are not the part of chemical reaction and its requirement with calculation and past data.
2. In chemical reaction, to indicate Serial number of import item with description (as per the license) below the reactants and if, indigenous item, then to indicate accordingly.
3. Concentration of *New Pentyl Zin Bromide Solution in THF* (Import Sl.No.1).
4. To give overall yield of each import chemical with justification.
5. End use of export item.

Case No.	66 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	JALAQUA INTERNATIONAL LLP
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00000722AM25
RA File Number	52AX04000032 AM25
Licence No and Date	5211008159/15/05/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Corrosive Solid, Basic, Organic, N.O.S (ChloramineT) (Chloramine Dihydrates)	1 kg.	1	Trichloroisocyanuric Acid	0.636 kg.

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

Case No.	67 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM REVIW00005651AM25
RA File Number	03AX04001364 AM25
Licence No and Date	0311034851/24/06/2024
Norms Committee Decision: The Committee considered the firm's request for a review of the ad-hoc norms. Upon examination, it was observed that the firm had not furnished any substantive technical justification or supporting information to warrant an enhancement of the existing norms. In the absence of any new material evidence or justification, the Committee found no reasonable grounds to review or revise the norms. Accordingly, it was decided to reject the request and maintain the status quo.	

Case No.	68 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	PANACEA BIOTEC PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00001565AM25
RA File Number	05AX04000957 AM25
Licence No and Date	0511026325/26/06/2024
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.
Paclitaxel (Protein-Bound Particles for Injectable Suspension 100 mg) Pacliall	35734 Vials	1	Albumin Human USP (25% Solution)	166 Litre

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

Case No.	69 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	JUBILANT GENERICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00001713AM25
RA File Number	05AX04001073 AM25
Licence No and Date	0511026456/03/07/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Paroxetine Hydrochloride 10mg Tablets	1 Number	1	Paroxetine Hydrochloride Hemihydrate	11.608 mg.
Paroxetine Hydrochloride 20mg Tablets	1 Number	2	Paroxetine Hydrochloride Hemihydrate	23.216 mg.
Paroxetine Hydrochloride 30mg Tablets	1 Number	3	Paroxetine Hydrochloride Hemihydrate	34.823 mg.

Paroxetine Hydrochloride 40mg Tablets	1 Number	4	Paroxetine Hydrochloride Hemihydrate	46.431 mg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	70 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00001763AM25
RA File Number	31AX04000098 AM25
Licence No and Date	3111003647/05/07/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. To give overall quantity of each chemical based on theoretical yield. 2. The theoretical value of by-product of caustic soda used by own industry. 3. Reason for using different type of solvent Methanol, Methylene Dichloride and Acetone. 4. To give weight of Hydrogen gas in kg. terms.	

Case No.	71 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00001820AM25
RA File Number	52AX04000089 AM25
Licence No and Date	5211008812/08/07/2024
Norms Committee Decision:	

The firm was called for Personal Hearing on 19/11/2024 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for Personal Hearing with relevant documents/information.

Case No.	72 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00001961AM25
RA File Number	03AX04001867 AM25
Licence No and Date	0311035566/16/07/2024
Norms Committee Decision:	
The firm was called for Personal Hearing on 19/11/2025, 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 sample of all import items	

Case No.	73 / NC/3/MEET/Nov/202526/10			
Case Status	Case Approved			
Party Name	DINAKARA LIFE SCIENCES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025			
HQ File Number	HQRNORM APPLY 00001982AM25			
RA File Number	09AX04000270 AM25			
Licence No and Date	0911007602/18/07/2024			
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:-				

			(3-CMP))	
		2	Sonneborn Double Blandol white Mineral oil	0.090 kg.
		3	alpha Cyclodextrin	0.957 kg.

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

Case No.	74 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00001994AM25
RA File Number	03AX04001885 AM25
Licence No and Date	0311035597/18/07/2024
Norms Committee Decision:	
The firm was called for Personal Hearing on 19/11/2025, 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 sample of all import items.	

Case No.	75 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00002279AM25
RA File Number	05AX04001164 AM25
Licence No and Date	0511026980/02/08/2024
Norms Committee Decision:	

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

Case No.	76 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	MEDIPRAT INTERNATIONAL (INDIA)
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00002899AM25
RA File Number	05AX04001556 AM25
Licence No and Date	0511027587/06/09/2024
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. Process flow of manufacturing export product and stepwise wastage incurred in the manufacturing. 2. Certificate of Analysis (CoA) for imported input products.	

Case No.	77 / NC/3/MEET/Nov/202526/10			
Case Status	Case Approved			
Party Name	KALPSUTRA GUJARAT			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025			
HQ File Number	HQRNORM APPLY 00002933AM25			
RA File Number	34AX04000467 AM25			
Licence No and Date	3411005382/09/09/2024			
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:-				

Undecylenic Aldehyde	1 kg.	1	Undecylenic Acid	1.30 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	78 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00002984AM25
RA File Number	09AX04000283 AM25
Licence No and Date	0911007924/11/09/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Valganciclovir Hydrochloride USP	1 kg.	1	Guanine	3.00 kg.
		2	CBZ -L-Valine	2.07 kg.
		3	Dimethyl formamide	13.00 kg.
		4	Dimethyl sulfoxide	2.82 kg.
		5	Isopropyl alcohol	5.00 kg.
		6	Trimethyl orthoacetate	2.92 kg.
		7	1,3-Diacetoxy-2-(acetoxymethoxy) propane	2.15 kg.

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

Case No.	79 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00002995AM25
RA File Number	03AX04002886 AM25
Licence No and Date	0311037072/11/09/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Clindamycin & Benzoyl Peroxide Gel 1% / 5% (Pack Size 25gm)	100000 Numbers	1	Clindamycin Phosphate USP	25.50 kg.
		2	Hydrous Benzoyl Peroxide USP	127.5 kg.
Clindamycin & Benzoyl Peroxide Gel 1% / 5% (Pack Size 35 gm)	100000 Numbers	3	Clindamycin Phosphate USP	35.70 kg.
		4	Hydrous Benzoyl Peroxide USP	178.50 kg.
Clindamycin & Benzoyl Peroxide Gel 1% / 5% (Pack Size 50 gm)	100000 Numbers	5	Clindamycin Phosphate USP	51.00 kg.
		6	Hydrous Benzoyl Peroxide USP	255.00 kg.
Clindamycin Phosphate Gel 1% (Pack Size 30 gm)	10000 Numbers	7	Clindamycin Phosphate USP	3.06 kg.
Clindamycin Phosphate Gel 1% (Pack Size 60 gm)	10000 Numbers	8	Clindamycin Phosphate USP	6.12 kg.

Adapalene & Benzoyl Peroxide Gel 0.1% / 2.5% (Pack Size 45 gm)	120000 Numbers	9	Hydrous Benzoyl Peroxide USP	137.70 kg.
Deriva CO Gel 0.1%/2.5% ZA (Adapalene & Benzoyl Peroxide Gel 0.1% / 2.5%) (Pack Size 45 gm)	100000 Numbers	10	Hydrous Benzoyl Peroxide USP	114.75 kg.
Deriva BPO Gel 0.1%/2.5% SA (Adapalene & Benzoyl Peroxide Gel 0.1% / 2.5%) (Pack Size 45 gm)	5128 Numbers	11	Hydrous Benzoyl Peroxide USP	5.885 kg.
Deriva BPO Gel 0.1%/2.5% SA (Adapalene & Benzoyl Peroxide Gel 0.1% / 2.5%) (Pack Size 45 gm)	5200 Numbers	12	Hydrous Benzoyl Peroxide USP	5.967 kg.
Clindamycin Phosphate Foam 1% (Pack Size 50 gm)	100000 Numbers	13	Clindamycin Phosphate USP	51.00 kg.
Clindamycin Phosphate Foam 1% (Pack Size 100 gm)	100000 Numbers		Clindamycin Phosphate USP	102.00 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	80 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003039AM25
RA File Number	09AX04000248 AM25
Licence No and Date	0911007949/13/09/2024
Norms Committee Decision: The representative of the firm appeared for the personal hearing and explained their case. However, the firm has admitted in the meeting that input at Sl. No.3 for the manufacture of the export product is not required. This constitutes a case of misdeclaration. Accordingly, the Committee decided to fix the norms on the basis of the technical data and the	

reply/submission made by the firm. The firm is also asked to submit bill of entries for imported items.

The Committee further directed the Regional Authority (RA) to initiate appropriate action against the firm under the provisions of the Foreign Trade (Development & Regulation) Act, 1992 and the rules made thereunder for the misdeclaration.

Case No.	81 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003195AM25
RA File Number	03AX04002984 AM25
Licence No and Date	0311037289/20/09/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Nitroglycerin Sublingual Tablets 0.3 mg (Net content of input item 1.95% Nitroglycerin on Lactose, USP is 54.16 kgs & Lactose Monohydrate NF 45.45 kgs & Sodium Starch Glycolate NF 12.32 kgs))	1 Number	1	1.95% Nitroglycerin on Lactose, USP	15.692 mg.
		2	Lactose Monohydrate NF	12.912 mg.
		3	Sodium Starch Glycolate NF	3.50 mg.
Nitroglycerin Sublingual Tablets 0.4 mg (Net content of input item 1.95% Nitroglycerin on Lactose, USP is 573.55 kgs & Lactose Monohydrate NF 217.64 kgs & Sodium Starch Glycolate NF 97.86 kgs))	1 Number	4	1.95% Nitroglycerin on Lactose, USP	20.923 mg.
		5	Lactose Monohydrate NF	7.784 mg.
		6	Sodium Starch Glycolate NF	3.50 mg.

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

Case No.	82 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003202AM25
RA File Number	05AX04001955 AM25
Licence No and Date	0511027881/20/09/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Oct/202526/9 dated 14/10/2025 against advance authorization No.0511031191 dated 04/03/2025, 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.
Meropenem Sodium Sterile (Meropenem for Injection) (Containing NLT 84% Sterile Meropenem)	1 kg.	1	Meropenem Trihydrate (Non Sterile)	0.8968 kg.

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

Case No.	83 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003222AM25
RA File Number	09AX04000405 AM25
Licence No and Date	0911008005/23/09/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1-([{(3R,3AS,6AR)- HEXAHYDROFURO[2M3-B] FURAN-3-YLOXY] CARBONYL}OXY)PYRROLIDINE- 2,5-DIONE / 2,5 DIOXOPYRROLIDIN-1-YL((3R, (1-([{(3R,3AS,6AR)- HEXAHYDROFURO[2M3-B] FURAN-3-YLOXY] CARBONYL}OXY)PYRROLIDINE- 2,5-DIONE / 2,5 DIOXOPYRROLIDIN-1- YL((3R,3AS,6AR)- HYXAHYDROFURO [2M3-b] FURAN-3- YL) CARBONATE)	1 kg.	1	(3AS, 4S, 6AR)-4-METHOXYTETRAHYDROFURO[3,4-B]FURAN-2(3H)-ONE(Naphthionic acid (1-naphthylamine-4-sulphonic acid), Para tolyl peri acid)	0.95 kg.
		2	SODIUM BORO HYDRIDE (HYDRIDES)	0.22 kg.
		3	TETRA HYDRO FURAN	5.04 kg.

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

Case No.	84 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	CADCHEM LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003280AM25
RA File Number	30AX04000313 AM25
Licence No and Date	3011005810/25/09/2024
Norms Committee Decision:	

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

Case No.	85 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003293AM25
RA File Number	08AX04001033 AM25
Licence No and Date	0811012739/26/09/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Diglycidyl ether of Neopentyl Glycol	1 kg.	1	Neopentyl Glycol	0.460 kg.
		2	Epichlorohydrin	0.940 kg.
		3	Caustic soda lye (Real)	0.385 kg.

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

Case No.	86 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	HOSTER LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003335AM25
RA File Number	09AX04000509 AM25

Licence No and Date	0911008057/27/09/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed
Ethyl-(2R,4S)-5-([1,1-biphenyl]-4-yl)-4-amino-2-methylpentanoate hydrochloride (Diloxanide furoate, Cimetidine, Oxytroclozanide, Famotidine: Other)	1 kg.	1	(2R,4S)-5-([1,1-biphenyl]-4-yl)-4-((tert-butoxycarbonyl)amino)-2-methylpentanoic acid (Other Nucleic Acids and their Salts)	1.21 kg.

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

Case No.	87 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	PRIGIV SPECIALTIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003427AM25
RA File Number	03AX04003148 AM25
Licence No and Date	0311037588/03/10/2024
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “<i>Rosacone</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.	88 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003432AM25
RA File Number	34AX04000497 AM25
Licence No and Date	3411005487/03/10/2024

Norms Committee Decision:

The firm was initially granted an Advance Authorisation for the export product “*Em Pentanoate (Ethyl-2-Methyl Pentanoate)*” 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.	89 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003433AM25
RA File Number	34AX04000550 AM25
Licence No and Date	3411005489/03/10/2024

Norms Committee Decision:

The firm was initially granted an Advance Authorisation for the export product “*Allyl Heptanoate*” 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.	90 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003450AM25
RA File Number	05AX04001783 AM25
Licence No and Date	0511028112/03/10/2024

Norms Committee Decision:

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

Case No.	91 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	BROOKS STERISCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003492AM25
RA File Number	34AX04000554 AM25
Licence No and Date	3411005493/04/10/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Meropenem for Injection USP 500 mg.	1 Number	1	Meropenem with Sodium Carbonate USP (Sterile Meropenem Trihydrate with Sodium Carbonate)	672.60 mg.
Meropenem for Injection USP 1000 mg.	1 Number	2	Meropenem with Sodium Carbonate USP(Sterile Meropenem Trihydrate with Sodium Carbonate)	1345.20 mg.
Meropenem for Injection USP 2000 mg.	1 Number	3	Meropenem with Sodium Carbonate USP(Sterile Meropenem Trihydrate with sodium Carbonate)	Not found in Drug Manufacturing Licence

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

Case No.	92 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred

Party Name	ENALTEC LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003514AM25
RA File Number	03AX04003311 AM25
Licence No and Date	0311037686/07/10/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete and balanced chemical reactions with Molecular weight and percentage yield on molar basis. 2. Name of the API produced from export it.	

Case No.	93 / NC/3/MEET/Nov/202526/10
Case Status	Case Rejected
Party Name	ENCEE AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003551AM25
RA File Number	32AX04000460 AM25
Licence No and Date	3211007682/08/10/2024
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “<i>Enamber/Kephalis/Tetrambrone</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.	94 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003598AM25
RA File Number	09AX04000471 AM25
Licence No and Date	0911008128/10/10/2024
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 furnish the following documents: 1. Tact report is July-August, 2023 which Advance Authorisation was issued in October, 2024. 2. Copy of revised Certificate of Analysis of import & export items relevant to present Advance Authorisation. 3. Revised Annexure to Appendix-4E.	

Case No.	95 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00003600AM25
RA File Number	09AX04000467 AM25
Licence No and Date	0911008130/10/10/2024
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 furnish the following documents:	

- I. Tst report is July-August, 2023 which Advance Authorisation was issued in October, 2024.
 II. Copy of revised Certificate of Analysis of import & export items relevant to present Advance Authorisation.
 III. Revised Annexure to Appendix-4E.

Case No.	96 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	ASTA BIOCHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00004300AM25
RA File Number	07AX04001295 AM25
Licence No and Date	0711012868/22/11/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. To give a balanced chemical reaction indicating molecular weight of both reactants and the products. 2. Yield of the reaction with justification.	

Case No.	97 / NC/3/MEET/Nov/202526/10
Case Status	Case Approved
Party Name	MOREPEN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00004305AM25
RA File Number	05AX04002794 AM25
Licence No and Date	0511029135/22/11/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Edoxaban Tosylate Monohydrate	1 kg.	1	Tert-Butyl((1R,2S,5S)-2-Amino-5- (Dimethyl Amino) Carbonyl) Cyclohexyl) Carbamate (EDN02)	0.808 kg.
		2	Ethyl {(5-Chloropyridin-2-YL) Amino}-Oxoacetate Hydrochloride (EDNS01)	0.750 kg.
		3	4,5,6,7-Tetrahydro-5-Methylthiazolo{5,4-C} Pyridine-2-Carboxylic Acid Hydrochloride (EDNS03)	0.500 kg.

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

Case No.	98 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00004315AM25
RA File Number	34AX04000689 AM25
Licence No and Date	3411005705/22/11/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	99 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00004318AM25
RA File Number	07AX04001351 AM25

Licence No and Date	0711012875/22/11/2024
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed that export description does not match with Drug Manufacturing Licence and working of norms applied. Hence it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant information / documents from the firm.	

Case No.	100 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00000087AM26
RA File Number	03AX04000001 AM26
Licence No and Date	0311042847/04/04/2025
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. To give balanced chemical reaction indicating molecular weight of both reactants and the products. 2. Yield of the reaction with justification. 3. Function of using chemicals other than reactants in the process, clearly indicating whether, it is solvent/neutralizer/catalyst etc. as the case may be	

Case No.	101 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	VIVA CORPORATION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00001034AM26
RA File Number	03AX04000827 AM26
Licence No and Date	0311044162/23/05/2025
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 chemistry with molecular weight, percentage yield and Stichometric balance

Case No.	102 / NC/3/MEET/Nov/202526/10
Case Status	Case Deferred
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202526/ 10 and 14/11/2025
HQ File Number	HQRNORM APPLY 00001449AM26
RA File Number	03AX04001143 AM26
Licence No and Date	0311044707/11/06/2025

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:-

- I. To give balanced chemical reaction indicating molecular weight of both reactants and the products.
- II. Yield of the reaction with justification.
- III. Function of using chemicals other than reactants in the process, clearly indicating whether, it is solvent/neutralizer/catalyst etc. as the case may be.