



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III**MEETING No.** NC/3/MEET/May/202627/3**DATED:** 26/05/2026

Minutes of the Norms Committee-3 Meeting NC/3/MEET/May/202526/3 dated 26/05/2026 under the Chairmanship of Shri Rakesh Kumar, Addl. DGFT for considering the cases/issues under Duty Exemption Scheme (Chapter-4) of the Foreign Trade Policy, 2023 pertaining to Chemical and Allied products falling under Chapter 29 and 30.

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

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

3. The Norms Committee has taken decisions only with respect to the technical aspect/ wastage norms. While redeeming the application, RAs should check that the applicant has fulfilled all

requirements as prescribed in policy/procedure, including those in notifications, public notices and policy circulars issued from time to time or any other provisions under FTP/HBP for issuance of Advance Authorization and regularisation of the case.

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

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

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00000125AM26
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: Decision:The representative of the firm appeared for the personal hearing and requested the fixation of norms in respect of Advance Authorisation No. 0910039411 dated 25.09.2009. The Norms Committee observed that the present application had been submitted under Para 4.06 of the HBP for the fixation of norms for the aforesaid authorisation, which was issued under Para 4.07 of the HBP. After detailed deliberation, the Committee decided to close the present application and call for a report from the concerned RA regarding the reasons for the non-fixation of norms in respect of Advance Authorisation No. 0910039411 dated 25.09.2009. The RA was further requested to furnish details of the imports and exports undertaken under the said authorisation to facilitate further examination of the matter.	

Case No.	2 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00000304AM27
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	3 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	SIGACHI INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00000787AM27
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Copy of Drug Manufacturing Licence. 2. Batch Manufacturing formula.	

Case No.	4 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	HEMA DYECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002356AM26
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case in accordance with the agenda and, upon examination, observed that the subject matter pertains to the fixation of SION. The ad-hoc norms (under the "No Norms" category) have already been fixed. The Committee further noted that the production/consumption data submitted by one of the manufacturers, M/s Vapi Spectrochem, pertains to a different raw material, namely Para Dimethoxy Aniline, instead of the subject raw material, Para Dimethoxy Benzene. Accordingly, the Committee decided to seek the following information/documents from the firm: 1. Production and consumption data relating to the export product and the correct raw material,	

i.e., Para Dimethoxy Benzene, for the last three years, duly certified by a Chartered Accountant and obtained from 2–3 manufacturers.

Case No.	5 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00004088AM26
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of the representative of the firm, and after due deliberation, the firm was advised that the quantity of the import item can be worked out by RA in line with SION A-412 (based on 100% potency of active ingredient). For any variation in potency envisaged, the firm may be advised to apply the application under para 4.07 with all necessary documentary evidence, Certificate of Analysis of actual import from foreign supplier, etc.	

Case No.	6 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	CYKLO PHARMA CHEM PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00004006AM26
RA File Number	032404000318 AM04
Licence No and Date	0310204913/29/05/2003
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any additional technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	7 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	WEXFORD LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00003783AM25
RA File Number	072404000382 AM14
Licence No and Date	0710101548/23/01/2014
Norms Committee Decision: The Committee considered the application of the firm and observed that the import item and export product are identical. The Committee further noted that, despite being provided with multiple opportunities, the firm failed to appear for the personal hearing. In view of the above, the Committee decided to reject the application.	

Case No.	8 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00007896AM24
RA File Number	072404000347 AM16
Licence No and Date	0710109255/12/01/2016
Norms Committee Decision: The Committee examined the application of the firm and noted that several opportunities were provided to the firm to appear for a personal hearing and present its case. However, the firm did not avail itself of these opportunities. In view of the above, the Committee decided to reject the application.	

Case No.	9 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	SHREE BANKEY BEHARI LAL FLAVORS

Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026																			
HQ File Number	HQRNORM REVIW00006890AM24																			
RA File Number	052404000067 AM19																			
Licence No and Date	0510406412/10/05/2018																			
Norms Committee Decision:																				
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-																				
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="3">L-Menthol /Menthol (Laveo) / Menthol (L) / Liquid Menthol</td> <td rowspan="3">1 kg.</td> <td>1</td> <td>Meta - Cresol Above 98.5% Pure</td> <td>0.992 kg.</td> </tr> <tr> <td>2</td> <td>Iso Propyl Alcohol</td> <td>0.750 kg.</td> </tr> <tr> <td>3</td> <td>Arrowzyme / Lipase Amano IME</td> <td>0.01 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	L-Menthol /Menthol (Laveo) / Menthol (L) / Liquid Menthol	1 kg.	1	Meta - Cresol Above 98.5% Pure	0.992 kg.	2	Iso Propyl Alcohol	0.750 kg.	3	Arrowzyme / Lipase Amano IME	0.01 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
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		2	Iso Propyl Alcohol	0.750 kg.																
		3	Arrowzyme / Lipase Amano IME	0.01 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	10 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	GLOBE TROTTERS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000620AM27
RA File Number	039404000713 AM19
Licence No and Date	0310825212/26/11/2018
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ampicillin Sodium Sterile BP	10000 kg.	1	Ampicillin Trihydrate IP/BP/USP	9390 kg.
		2	Acetonitrile (ACN)	Not required.
		3	Methylene Chloride	
		4	Triethylamine	
		5	Ethyl Acetate	

Note: The above norms are for regularization and closure purpose only.

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

Case No.	11 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	018205000499AM20
RA File Number	039404000373 AM20
Licence No and Date	0310830887/07/08/2019
Norms Committee Decision:	

The firm was initially granted an Advance Authorisation for the export product “Valencene 80 & Dodecane Rec Ex Valencene” 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.	12 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000267AM27
RA File Number	092404000313 AM20
Licence No and Date	0910067997/13/09/2019
Norms Committee Decision:	
The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of the representative of the firm, and after due deliberation, the firm may be advised to get the Advance Authorisation amended with a reasonable import quantity against above export product.	

Case No.	13 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	STERLING AUXILIARIES PVT LTD

Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000410AM27
RA File Number	039504000340 AM20
Licence No and Date	0310831915/30/09/2019
Norms Committee Decision:	
The Committee considered the application of the firm. It was observed that the firm had not furnished the specific information sought by the Committee during its meeting held on 30.06.2025. In view of the non-submission of the requisite information, the Committee decided to reject the firm's application.	

Case No.	14 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	STERLING AUXILIARIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000417AM27
RA File Number	039504000135 AM20
Licence No and Date	0310831916/30/09/2019
Norms Committee Decision:	
The Committee considered the application of the firm. It was observed that the firm had not furnished the specific information sought by the Committee during its meeting held on 30.06.2025. In view of the non-submission of the requisite information, the Committee decided to reject the firm's application.	

Case No.	15 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
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 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.	16 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	STERLING AUXILIARIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000460AM27
RA File Number	039504000492 AM21
Licence No and Date	0310839386/06/11/2020
Norms Committee Decision:	
The Committee considered the application of the firm. It was observed that the firm had not furnished the specific information sought by the Committee during its meeting held on 30.06.2025. In view of the non-submission of the requisite information, the Committee decided to reject the firm's application.	

Case No.	17 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	STERLING AUXILIARIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000458AM27
RA File Number	03AA04074026 AM22
Licence No and Date	0311006960/15/09/2021
Norms Committee Decision:	
The Committee considered the application of the firm. It was observed that the firm had not furnished the specific information sought by the Committee during its meeting held on 25.02.2025 and 03.12.2025. In view of the non-submission of the requisite information, the Committee decided to reject the firm's application.	

Case No.	18 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	STERLING AUXILIARIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000433AM27
RA File Number	03AA04082803 AM22
Licence No and Date	0311007171/23/09/2021
Norms Committee Decision: The Committee considered the application of the firm. It was observed that the firm had not furnished the specific information sought by the Committee during its meeting held on 25.02.2025 and 03.12.2025. In view of the non-submission of the requisite information, the Committee decided to reject the firm's application.	

Case No.	19 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000539AM27
RA File Number	52AX04000039 AM23
Licence No and Date	5211002485/13/05/2022
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	20 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
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 noted that the firm has proposed the import of Soda Ash, which falls under the restricted category of imports. In view of the policy restriction, the Committee decided to reject the application. The Committee also directed the concerned RA to undertake a visit to the firm's factory premises and verify the records pertaining to the utilisation of Soda Ash and other raw materials claimed for the manufacture of the export product. The findings of the verification, along with supporting details, may be furnished to the Norms Committee and Policy-4 Section for appropriate action.	

Case No.	21 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00004127AM25
RA File Number	03AX04002151 AM23
Licence No and Date	0311016241/11/07/2022
Norms Committee Decision: The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of the representative of the firm, and after due deliberation the firm was advised to get the Advance Authorisation amended for actual import.	

Case No.	22 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000140AM27
RA File Number	03AX04004371 AM23

Licence No and Date	0311019903/12/12/2022
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 relevant information / documents from the firm.	

Case No.	23 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	SARAL CHEMTECH LLP
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00000865AM24
RA File Number	33AX04000105 AM23
Licence No and Date	3311001206/16/05/2023
Norms Committee Decision: The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the firm was advised to get Advance Authorisation amended for actual import.	

Case No.	24 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00005177AM26
RA File Number	03AX04001433 AM24
Licence No and Date	0311024964/28/06/2023
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any additional technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	25 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00006203AM26
RA File Number	34AX04000209 AM24
Licence No and Date	3411003978/02/08/2023
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “Cyclo Hexyl Salicylate” under Para 4.07 of the Handbook of Procedures (HBP). However, as per Para 4.11(b) of the Foreign Trade Policy (FTP) 2023, products falling under the category of perfume or perfumery compounds are ineligible for authorisation under Para 4.07 and are mandatorily required to be processed under Para 4.06 of the HBP. It was observed that the firm obtained the authorisation by misdeclaring that its application was covered under the provisions of Para 4.07, and has not furnished any technical justification/information for the export product. Accordingly, the Committee found no merit in fixing the norms and decided to reject the application. The RA shall ensure that the said authorisation is regularised by recovery of applicable Customs duty along with interest. Further, the RA should also submit a report on how this authorisation was issued under Para 4.07 of HBP, to the Chairperson of the Norms Committee and to PC-4 Section, DGFT Headquarters. The RA concerned may take further necessary action in line with the above decision of the Committee.	

Case No.	26 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00005541AM26
RA File Number	03AX04002023 AM24
Licence No and Date	0311026196/10/08/2023

Norms Committee Decision:

The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents:

1. Copy of Advance Authorisation in support of 4th import item.

Case No.	27 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	STANEX DRUGS AND CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00005456AM24
RA File Number	09AX04000507 AM24
Licence No and Date	0911005765/05/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Heparin Sodium Injection 25000IU	75000 Vials	1	Low grade Glycosamino Glycans or Glycosamino glycans (25000 Mega)	15.4 kg.
Heparin Sodium Injection 5000IU	75000 Vials	2	Low grade Glycosamino Glycans or Glycosamino glycans (25000 Mega)	3.08 kg.

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

Case No.	28 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00008930AM24
RA File Number	03AX04003005 AM24
Licence No and Date	0311027533/03/10/2023
Norms Committee Decision: The Committee considered the request of firm for the fixation of ad-hoc norms, and it has been observed that the firm vide e-mail dated 22/05/2026 has informed that they have closed the licence and requested to withdraw the application from the portal. Therefore, it was decided to close the application of the firm.	

Case No.	29 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00006697AM26
RA File Number	05AX04002118 AM24
Licence No and Date	0511021548/16/10/2023
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any additional technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	30 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000628AM27
RA File Number	03AX04003186 AM24
Licence No and Date	0311027939/17/10/2023
Norms Committee Decision: The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.	

Case No.	31 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00005179AM26
RA File Number	03AX04003793 AM24
Licence No and Date	0311028844/22/11/2023
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any additional technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	32 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00005283AM26
RA File Number	34AX04000494 AM24
Licence No and Date	3411004386/29/11/2023

Norms Committee Decision:

The firm was initially granted an Advance Authorisation for the export product “Anethole (para-Methoxy phenlpropene)” 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/May/202627/3
Case Status	Case Rejected
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00007173AM24
RA File Number	05AX04002730 AM24
Licence No and Date	0511022438/04/12/2023

Norms Committee Decision:

The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of the representative of the firm, and it was observed that no technical expert was present during the hearing to explain the deficiency raised by the Committee; therefore, it was decided to reject the application of the firm.

Case No.	34 / NC/3/MEET/May/202627/3
Case Status	Case Approved

Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00007728AM24
RA File Number	09AX04000875 AM24
Licence No and Date	0911006481/03/01/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Posaconazole	1 kg.	1	3R,5R)-5-(2,4-difluorophenyl)-5-(iodomethyl) tetrahydrofuran-3-yl) methanol	0.855 kg.
		2	2-[(1S,2S)-1-ethyl-2-bezyloxypropyl]-2,4-dihydro-4-[4-[4-(4-hydroxyphenyl)-1-piperazinyl]phenyl]- 3H-1,2,4-Triazol-3-one	1.23 kg.
		3	(S)-Methyl Lactate	Not required
		4	Dichloromethane / Methylene dichloride	2.00 kg.
		5	Methanol	1.50 kg.
		6	Palladium metal	Not shown in reaction

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

Case No.	35 / NC/3/MEET/May/202627/3				
Case Status	Case Approved				
Party Name	NEOGEN CHEMICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026				
HQ File Number	HQRNORM REVIW00005504AM26				
RA File Number	03AX04004498 AM24				
Licence No and Date	0311029998/08/01/2024				
Norms Committee Decision:					
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below.:-					

Case No.	36 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00008367AM24
RA File Number	52AX04000336 AM24
Licence No and Date	5211007280/06/02/2024
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-{1-[(2S)-2-Aminopropyl]-1H-Pyrazole-3-yl}-2-Chlorobenzonitrile)	1 kg.	1	1-(2-Tetrahydropyranyl) -1H Pyrazole-5-Boronic Acid Pinacol Ester(1-(2-Tetrahydropyranyl)-1H Pyrazole-5-Boronic Acid Pinacol Ester (1-(Tetrahydro 2 H Pyran 2yl) -5-(4,4,5,5 Tetramethyl 1,3,2 Dioxaborolane-2-yl)-1H-Pyrazole))	1.50 kg.
		2	4-Bromo-2-Chloro Benzonitrile	1.165 kg.
		3	2-Amino-1-Propanol (S-(+)-2-Amino-1-Propanol) ((S)-2-aminopropan-1-ol (L-Alininol))	0.46 kg.
		4	Di Tert Butyl Dicarboxylate	1.34 kg.
		5	Di-isopropyl azodicarboxylate	1.034 kg.
		6	Triphenylphosphine	1.89 kg.

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

Case No.	37 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00006714AM26
RA File Number	05AX04003618 AM24
Licence No and Date	0511023881/09/02/2024
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the norms given are based on approved composition in the Drug Manufacturing Licence and wastage as per SION. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	38 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000631AM27
RA File Number	03AX04005326 AM24
Licence No and Date	0311031507/27/02/2024
Norms Committee Decision: The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.	

Case No.	39 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	ASTEC LIFESCIENCES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00005181AM26
RA File Number	03AX04005541 AM24
Licence No and Date	0311031703/05/03/2024
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any additional technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	40 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00006698AM26
RA File Number	05AX04003839 AM24
Licence No and Date	0511024393/07/03/2024
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the norms given are based on approved composition in Drug Manufacturing Licence and wastage as per SION. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	41 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	GALAXY SURFACTANTS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00004387AM25
RA File Number	03AX04006008 AM24
Licence No and Date	0311032549/27/03/2024
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Lauric monoethanolamide (Galaxy 200)	1 kg.	1	Lauric Acid	0.8268 kg.
		2	Mono Ethanol Amine	0.2552 kg.

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

Case No.	42 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	SYNERGIA SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00000333AM25
RA File Number	03AX04000023 AM25
Licence No and Date	0311033222/19/04/2024
Norms Committee Decision: The committee considered the application of the firm, and it has been observed that various opportunities were given to the firm, but the firm has not appeared for a personal hearing before the committee to explain their case; therefore, the committee decided to reject the application of the firm.	

Case No.	43 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	APTRA SYNTHESIS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00000952AM25
RA File Number	26AX04000006 AM25
Licence No and Date	2611001464/28/05/2024
Norms Committee Decision: The committee considered the application of the firm, and it has been observed that various opportunities were given to the firm, but the firm has not appeared for a personal hearing before the committee to explain their case; therefore, the committee decided to reject the application of the firm.	

Case No.	44 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000511AM27
RA File Number	03AX04000876 AM25
Licence No and Date	0311034159/28/05/2024
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any additional technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	45 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000259AM27
RA File Number	03AX04001186 AM25
Licence No and Date	0311034574/13/06/2024
Norms Committee Decision:	

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

Case No.	46 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000260AM27
RA File Number	03AX04001135 AM25
Licence No and Date	0311034573/13/06/2024
Norms Committee Decision:	
The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.	

Case No.	47 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	SUPRIYA LIFESCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00005576AM26
RA File Number	03AX04001271 AM25
Licence No and Date	0311034600/13/06/2024
Norms Committee Decision:	
<i>The Committee considered the request of the firm for review of ad-hoc norms and it was decided to extend the ad-hoc norms given earlier in Advance Authorisation No. 0311031241 dated 15.02.2024 for another period of one year, as per the details indicated below:-</i>	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
RIBOFLAVIN SODIUM PHOSPHATE HYDRATE EP 11.2	1 kg.	1	VITAMIN B2 OR RIBOFLAVIN	1.30 kg.
		2	PYRIDINE	2.00 kg.
		3	ACETONITRILE	1.73 kg.
		4	PHOSPHORUS OXYCHLORIDE	2.00 kg.

Note:

- I. The firm will produce improvement in the consumption norms after a period of one year.
- II. Further cases after one year will be decided based on improved consumption norms.

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

Case No.	48 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001820AM25
RA File Number	52AX04000089 AM25
Licence No and Date	5211008812/08/07/2024
Norms Committee Decision:	
<i>The Committee examined the request of the firm for fixation of ad-hoc norms . After due</i>	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-{1-[(2S)-2-Aminopropyl]-1H-Pyrazole-3-yl}-2-Chlorobenzonitrile)	1 kg.	1	1-(2-Tetrahydropyranyl) -1H Pyrazole-5-Boronic Acid Pinacol Ester(1-(2-Tetrahydropyranyl)-1H Pyrazole-5-Boronic Acid Pinacol Ester (1-(Tetrahydro 2 H Pyran 2yl) -5-(4,4,5,5 Tetramethyl 1,3,2 Dioxaborolane-2-yl)-1H-Pyrazole))	1.50 kg.
		2	4-Bromo-2-Chloro Benzonitrile	1.165 kg.
		3	2-Amino-1-Propanol (S-(+)-2-Amino-1-Propanol) ((S)-2-aminopropan-1-ol (L-Alininol))	0.46 kg.
		4	Di Tert Butyl Dicarbonate	1.34 kg.
		5	Di-isopropyl azodicarboxylate	1.034 kg.

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

Case No.	49 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001994AM25
RA File Number	03AX04001885 AM25
Licence No and Date	0311035597/18/07/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against advance authorization No.0311026174 dated 09/08/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sodium Chloride 0.9% 50 ml	1 Number	1	Sodium Chloride (SANAL) (EP)	0.4725 gm.
		6	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage
		11	BOP Injection (Art. 0434481)	Net content in export + 1% wastage
		16	SSC Infusion (0434181)	Net content in export + 1% wastage
		21	SSC Injection (Art. 0434371)	Net content in export + 1% wastage
		26	SF9-11 195/95 Prim. Film (0369581)	Net content in export + 1% wastage
		33	OFR2-11 150/524 for 50 and 100ml	Net content in export + 1%

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

		42	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage
Sodium Chloride 0.9 % 250 ml	1 Number	3	Sodium Chloride (SANAL) (EP)	2.3625 gm.
		8	BOP Infusion (Art.No 0434171)	Net content in export + 1% wastage
		13	BOP Injection (Art. 0434481)	Net content in export + 1% wastage
		18	SSC Infusion (0434181)	Net content in export + 1% wastage
		23	SSC Injection (Art. 0434371)	Net content in export + 1% wastage
		28	SF9-11 195/100 Prim. Film (Art.0369591)	Net content in export + 1% wastage
		35	OFR2-11 150/524 for 50 and 100 ml (0369701)	Net content in export + 1% wastage
		38	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage
		43	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage
Sodium Chloride 0.9% 500 ml	1 Number	4	Sodium Chloride	4.725 gm.

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

		15	BOP Injection (Art. 0434481)	Net content in export + 1% wastage
		20	SSC Infusion (0434181)	Net content in export + 1% wastage
		25	SSC Injection (Art. 0434371)	Net content in export + 1% wastage
		30	SF9-11 195/140 Prim. film (Art.0369631)	Net content in export + 1% wastage
		32	OFR2-11 120/524-500 ml and 1000 ml (0369681)	Net content in export + 1% wastage
		40	UFR2-11 150/524-50 ml to 1000 (0369661)	Net content in export + 1% wastage
		45	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage

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

Case No.	50 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	DINAKARA LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000178AM27
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 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.	51 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002051AM25
RA File Number	34AX04000849 AM24
Licence No and Date	3411005190/22/07/2024
Norms Committee Decision: The Representative of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the firm was advised to submit the following documents:- 1. Copy of Shipping Bill and Bill of Entry 2. Justification for description on of import and export item which are not matching with Drug Manufacturing Licence (DML).	

Case No.	52 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000632AM27
RA File Number	03AX04002117 AM25
Licence No and Date	0311036002/01/08/2024
Norms Committee Decision: The Committee examined the application of the firm and noted that the export product is a well-	

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

Case No.	53 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002279AM25
RA File Number	05AX04001164 AM25
Licence No and Date	0511026980/02/08/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-(Dimethyl Amino)-Pyridine	1 kg.	1	Alumino Silicate Catalyst	0.019 kg.
		2	Denatured Ethyl Alcohol	1.13 kg.
		3	Methanol	0.70 kg.
		4	Thionyl Chloride	1.44 kg.
		5	Dimethyl Formamide	0.886 kg.
		6	Toluene	0.203 kg.

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

Case No.	54 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	CHROMO LABORATORIES INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00006640AM26
RA File Number	09AX04000325 AM25
Licence No and Date	0911007740/14/08/2024
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix-4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. The commercial value of by-product Acetone obtained during process, supported by invoice/s.	

Case No.	55 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000518AM26
RA File Number	03AX04002550 AM25
Licence No and Date	0311036761/29/08/2024
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the norms given are based on approved composition in Drug Manufacturing Licence and wastage as per SION. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	56 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	PRIVI FINE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000633AM27
RA File Number	03AX04002673 AM25
Licence No and Date	0311036880/04/09/2024
Norms Committee Decision: The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.	

Case No.	57 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	PRIVI FINE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000635AM27
RA File Number	03AX04002672 AM25
Licence No and Date	0311036881/04/09/2024
Norms Committee Decision: The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.	

Case No.	58 / NC/3/MEET/May/202627/3
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Case Status	Case Deferred
Party Name	MEDIPRAT INTERNATIONAL (INDIA)
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
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 case as per the agenda and after examination, it was observed the imported inputs bulk Deproteinized Calf Serum Extract Solution 200 mg/ml to make Protoseril (Deproteinized Calf Blood Extract each 1 ml. contains 40 mg/1 ml. Injections of various strength. It is also not clear, how the import item is used in manufacturing of export item. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Give all the steps in the form of flow chart with a mention of wastage incurred at each step. 2. Provide the information on marker and Certificate of Analysis (CoA) to confirm that an import item has 200 mg/ml of Deproteinized Calf Serum Extract Solution.	

Case No.	59 / NC/3/MEET/May/202627/3			
Case Status	Case Approved			
Party Name	METROCHEM API PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026			
HQ File Number	HQRNORM APPLY 00003039AM25			
RA File Number	09AX04000248 AM25			
Licence No and Date	0911007949/13/09/2024			
Norms Committee Decision:				
<i>The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below.:-</i>				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Posaconazole	1 kg.	1	3R,5R)-5-(2,4-difluorophenyl)-5-(iodomethyl) tetrahydrofuran-3-yl) methanol	0.855 kg.
		2	2-[(1S,2S)-1-ethyl-2-bezyloxypropyl]-2,4-dihydro-4-[4-[4-(4-hydroxyphenyl)-1-piperazinyl]phenyl]- 3H-1,2,4-Triazol-3-one	1.23 kg.
		3	(S)-Methyl Lactate	Not required
		4	Dichloromethane / Metrhylene dichloride	2.00 kg.
		5	Methanol	1.50 kg.
		6	Palladium metal	Not shown in reaction
		7	Iso propyl alcohol	2.00 kg.

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

Case No.	60 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00006694AM26
RA File Number	05AX04001968 AM25
Licence No and Date	0511027793/18/09/2024
Norms Committee Decision:	

The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the norms given are based on approved composition in Drug Manufacturing Licence and wastage as per SION. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.

Case No.	61 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00003178AM25
RA File Number	05AX04001863 AM25
Licence No and Date	0511027857/20/09/2024
Norms Committee Decision: The representative of the firm attended the personal hearing and presented the firm's case. Upon examination, the Committee observed that several inputs sought under the authorisation do not appear to be used in the manufacture of the export product. Accordingly, the firm was advised to get the authorisation suitably amended to align the approved inputs with the actual manufacturing requirements of the export product	

Case No.	62 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00003321AM25
RA File Number	05AX04002052 AM25
Licence No and Date	0511028003/27/09/2024
Norms Committee Decision: The representative of the firm attended the personal hearing and presented the firm's case. Upon examination, the firm was advised to get the authorisation suitably amended to align the approved inputs with the actual manufacturing requirements of the export product.	

Case No.	63 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000280AM27
RA File Number	34AX04000497 AM25
Licence No and Date	3411005487/03/10/2024
Norms Committee Decision: The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.	

Case No.	64 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000281AM27
RA File Number	34AX04000550 AM25
Licence No and Date	3411005489/03/10/2024
Norms Committee Decision: The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.	

Case No.	65 / NC/3/MEET/May/202627/3
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Case Status	Case Approved													
Party Name	ENALTEC LABS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026													
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 case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/2 dated 28/04/2026 against advance authorization No.0311041804 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Midodrine Hydrochloride USP</td><td>1 kg.</td><td>1</td><td>2-Amino-1-(2,5dimethoxyphenyl) ethanone hydrochloride</td><td>1.76 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Midodrine Hydrochloride USP	1 kg.	1	2-Amino-1-(2,5dimethoxyphenyl) ethanone hydrochloride	1.76 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Midodrine Hydrochloride USP	1 kg.	1	2-Amino-1-(2,5dimethoxyphenyl) ethanone hydrochloride	1.76 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	66 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	ENCEE AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00005418AM26
RA File Number	32AX04000460 AM25
Licence No and Date	3211007682/08/10/2024
Norms Committee Decision:	
The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier	

decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.

Case No.	67 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000282AM27
RA File Number	34AX04000564 AM25
Licence No and Date	3411005540/15/10/2024
Norms Committee Decision: The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.	

Case No.	68 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000283AM27
RA File Number	34AX04000597 AM25
Licence No and Date	3411005544/16/10/2024
Norms Committee Decision: The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.	

Case No.	69 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000254AM27
RA File Number	03AX04003565 AM25
Licence No and Date	0311038045/18/10/2024
Norms Committee Decision: The Committee examined the application of the firm and noted that the export product is a well-established perfumery compound with widespread use as a synthetic aroma chemical. Considering the nature and established usage of the product, the Committee decided to uphold its earlier decision and advised the firm to seek fixation of norms under Para 4.06 of the HBP. Accordingly, the application was rejected.	

Case No.	70 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00000537AM27
RA File Number	52AX04000217 AM25
Licence No and Date	5211010354/18/10/2024
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the firm had not furnished any additional technical justification or supporting information for the proposed enhancement. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	71 / NC/3/MEET/May/202627/3
Case Status	Case Rejected

Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00004476AM26
RA File Number	05AX04002457 AM25
Licence No and Date	0511028610/28/10/2024
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the norms given are based on approved composition in Drug Manufacturing Licence and wastage as per SION. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo	

Case No.	72 / NC/3/MEET/May/202627/3										
Case Status	Case Approved										
Party Name	ASTA BIOCHEMICALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026										
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 case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against advance authorization No.0711014690 dated 11/06/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Calcium Thioglycolate</td><td>1 kg.</td><td>1</td><td>Thioglycolic Acid</td><td>0.927 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Calcium Thioglycolate	1 kg.	1	Thioglycolic Acid	0.927 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Calcium Thioglycolate	1 kg.	1	Thioglycolic Acid	0.927 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	73 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
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 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.	74 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM REVIW00006699AM26
RA File Number	05AX04002820 AM25
Licence No and Date	0511029128/22/11/2024
Norms Committee Decision: The Committee considered the firm's request for review of the ad-hoc norms. However, it was observed that the norms given are based on approved composition in the Drug Manufacturing Licence and wastage as per SION. Accordingly, the Committee did not find any merit in the request and decided to reject the case, thereby maintaining the status quo.	

Case No.	75 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00005503AM26
RA File Number	NA
Licence No and Date	0811013677/02/01/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Nov/202425/10 dated 22/11/2024 against DGFT (HQ) File No.HQRNORMAPPLY00003140AM25, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
AZITHROMYCIN ORAL SUSPENSION USP 100MG/5ML (300MG/15ML BOTTLE) ((ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP EQUIVALENT TO AZITHROMYCIN USP - NET WT. 132.597 KGS))	1 Number	1	AZITHROMYCIN DIHYDRATE USP	330.12 mg.
		2	SUCROSE NF FINE GRADE (COMPRESSUC PS)	11616.00 mg.
AZITHROMYCIN ORAL SUSPENSION USP 200MG/5ML (600MG/15ML BOTTLE) ((ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP EQUIVALENT TO AZITHROMYCIN USP - NET WT. 530.382 KGS))	1 Number	3	AZITHROMYCIN DIHYDRATE USP	660.24 mg.
		4	SUCROSE NF FINE GRADE (COMPRESSUC PS)	11616.00 mg.
AZITHROMYCIN ORAL SUSPENSION USP 200MG/5ML (900MG/22.5ML BOTTLE) ((ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP EQUIVALENT TO AZITHROMYCIN USP - NET WT. 278.973 KGS))	1 Number	5	AZITHROMYCIN DIHYDRATE USP	990.36 mg.
		6	SUCROSE NF FINE GRADE (COMPRESSUC PS)	17424.00 mg.

AZITHROMYCIN ORAL SUSPENSION USP 200MG/5ML (1200MG/30ML BOTTLE) ((ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP EQUIVALENT TO AZITHROMYCIN USP - NET WT. 2174.778 KGS))	1 Number	7	AZITHROMYCIN DIHYDRATE USP	1320.48 mg.
		8	SUCROSE NF FINE GRADE (COMPRESSUC PS)	23232.00 mg.

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

Case No.	76 / NC/3/MEET/May/202627/3										
Case Status	Case Approved										
Party Name	VIVA CORPORATION PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026										
HQ File Number	HQRNORM APPLY 00001034AM26										
RA File Number	03AX04000827 AM26										
Licence No and Date	0311044162/23/05/2025										
Norms Committee Decision:											
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below.:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Calcium Laurate</td><td>1 kg.</td><td>1</td><td>Lauric Acid</td><td>0.947</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Calcium Laurate	1 kg.	1	Lauric Acid	0.947
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Calcium Laurate	1 kg.	1	Lauric Acid	0.947							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	77 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ZENITH DYEINTERMEDIATES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00003610AM26
RA File Number	NA
Licence No and Date	0311044458/04/06/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aug/202425/8 dated 28/08/2024 against Advance Authorisation No.0311033314 dated 24/04/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NAS-5((2-DIAZO-1-NAPTHOL-5-SULFONIC ACID, SODIUM SALT))	1 kg.	1	Tobias Acid (Purity 97%)	0.70 kg.

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

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

Case No.	78 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	AARTI PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001799AM26
RA File Number	03AX04001592 AM26

Licence No and Date	0311045241/01/07/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202526/5 dated 30/06/2025 against Advance Authorisation No.0311038930 dated 22/11/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Theophylline (Anhydrous)	1 kg.	1	Cyano Acetic Acid 70%	0.89 kg.
Note: NC also decided to make new SION for the above export product.				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	79 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	RISHABH METALS & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001800AM26
RA File Number	03AX04001508 AM26
Licence No and Date	0311045242/01/07/2025
Norms Committee Decision:	
The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents:	
1. Specific nitrile function compound to be exported with its structural formula and molecular weight.	

2. Specific items to be imported since other items are shown indiginous

Case No.	80 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	SIDDHARTH CARBOCHEM PRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001801AM26
RA File Number	03AX04001472 AM26
Licence No and Date	0311045243/01/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
HEXYL SALICYLATE	1 kg.	1	SALICYLIC ACID	0.661 kg.
		2	N HEXANOL	0.636 kg.
		3	HDPE RESIN PACKING	Relevant, as per Packing Policy & General Notes.

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

Case No.	81 / NC/3/MEET/May/202627/3
Case Status	Case Approved

Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001805AM26
RA File Number	03AX04001600 AM26
Licence No and Date	0311045250/01/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxyleb Capsule (Doxycycline Capsules Bp) 100 mg. (In Packing of 10 X 10's , 10 x 100's & 1000's. Qty Consumed Of Exempt Material Doxycycline Hyclate BP- 115.400 mg / Capsule.)	1 Number Tablet	1	Doxycycline Hyclate BP	117.72 mg

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

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

Case No.	82 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001807AM26
RA File Number	09AX04000309 AM26
Licence No and	0911009941/01/07/2025

Date

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against Advance Authorisation No.0911009916 dated 26/06/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Liraglutide Injection 18 mg/3 ml (6 mg/mL) 1x3's ((Each 3 ml contains Liraglutide 18 mg) Fill Volume- 3.3 ml)	1 Number	1	Liraglutide (API- (Water Content - upto 6.4%, Sodium Ion- 1.8%)=8.20%)	19.8 mg/ Vial
		2	3.0 mL Pre - Crimped Glass Siliconized Cartridge (Cartridge EZ-Fill Nexa VB 3mL)	Relevant, as per Packing Policy & General Notes.
		3	BD Vystra Disposable Pen Body Subassembly with Purple Colour Dose Button (VYSTRAS BSA FR PL 284C BTN 2685C 50IU)	Relevant, as per Packing Policy & General Notes.
		4	BD Vystra Disposable Pen Printed Cartridge Holder (VYSTRAS CARTRIDGE HOLDER PRINTED 0.6-15)	Relevant, as per Packing Policy & General Notes.
		5	BD Vystra Disposable Pen Cap (VYSTRAS CAP PL MODERN 284C)	Relevant, as per Packing Policy & General Notes.

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

Case No.	83 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001808AM26
RA File Number	09AX04000308 AM26
Licence No and Date	0911009942/01/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against Advance Authorisation No.0911009916 dated 26/06/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Liraglutide Injection 18 mg/3 ml (6 mg/mL) 1x3's ((Each 3 ml contains Liraglutide 18 mg) Fill Volume- 3.3 ml)	1 Number	1	Liraglutide (API- (Water Content - upto 6.4%, Sodium Ion- 1.8%)=8.20%)	19.8 mg/ Vial
		2	3.0 mL Pre - Crimped Glass Siliconized Cartridge (Cartridge EZ-Fill Nexa VB 3mL)	Relevant, as per Packing Policy & General Notes.
		3	BD Vystra Disposable Pen Body Subassembly	Relevant, as per Packing

			with Purple Colour Dose Button (VYSTRA BSA FR PL 284C BTN 2685C 50IU)	Policy & General Notes.
		4	BD Vystra Disposable Pen Printed Cartridge Holder (VYSTRA CARTRIDGE HOLDER PRINTED 0.6-15)	Relevant, as per Packing Policy & General Notes.
		5	BD Vystra Disposable Pen Cap (VYSTRA CAP PL MODERN 284C)	Relevant, as per Packing Policy & General Notes.

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

Case No.	84 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	CAPTAVIS BIOCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001824AM26
RA File Number	08AX04000527 AM26
Licence No and Date	0811015452/02/07/2025
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Copy of Drug Manufacturing Licence (DML).	

2. Copy of Master Batch Formula.

Case No.	85 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001877AM26
RA File Number	52AX04000088 AM26
Licence No and Date	5211014866/04/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against Advance Authorisation No.5211005508 dated 21/08/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

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

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

Case No.	86 / NC/3/MEET/May/202627/3
Case Status	Case Approved

Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001880AM26
RA File Number	03AX04001691 AM26
Licence No and Date	0311045385/05/07/2025

Norms Committee Decision:

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

Sl. No.	Export Product	Quantity
1	Medical Cream, Ointment, Gel (Fluorouracil Cream 5% 15 Gm Tot Wt1 Number 6378.11 Kgs, Net Cont: 5-Fluorouracil 318.90 Kgs, Stearyl Alco 956.71 Kgs, Propylene 765.37 Kgs, Methyl para 1.91 Kgs, Propyl para 1.27 Kgs, Tween 60 318.90 Kgs, white petrolatum 1403.18 Kgs))	

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

Note:

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

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

Case No.	87 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001898AM26
RA File Number	03AX04001714 AM26
Licence No and Date	0311045358/07/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202526/3 dated 04/06/2025 against Advance Authorisation No.0311038087 dated 21/10/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Moxileb-250 dt.Amoxicillin Tablet 250 mg ((Each Tablet Containing Amoxicillin Trihydrate Equivalent To 250 mg of Amoxicillin). Net Content of Import/Exempt Material Used In Export Product 1)Amoxicillin Trihydrate BP (Compacted) -157.853 kgs (Excl 2% Wastage))	1 Number	1	Amoxicillin Trihydrate BP Compacted	292.639 mg.
Moxileb-250 Capsule. (Amoxicillin Capsule 250 mg) ((Each Capsule Containing Amoxicillin Trihydrate Equoalent To 250 mg of Amoxicillin). Net Content of Import/Exempt Material Used In Export Product 1) Amoxicillin Trihydrate BP (Compacted) -1205.402 kgs (Excl 2% Wastage))	1 Number	2	Amoxicillin Trihydrate BP Compacted	292.639 mg.
Moxileb-500 Capsule. (Amoxicillin	1 Number	3	Amoxicillin	585.28 mg.

Capsule 500 mg). ((Each Capsule Containing Amoxicillin Trihydrate Equivalent To 500 mg of Amoxicillin). Net Content of Import/Exempt Materialused In Export Product 1) Amoxicillin Trihydrate BP (Compacted) -5737.13 kgs (Excl 2% Wastage))			Trihydrate BP Compacted	
Moxileb Oral Suspension Amoxicillin Oral Suspension (Amoxicillin Syrup) 125 mg/100 ml Bottle. ((Each 5 ml Contains Amoxicillin Trihydrate Euqivalent To 125 mg of Amoxicillin). Net Content of Import/Exempt Material Used In Export Product 1) Amoxicillin Trihydrate BP - (Compacted) - 60.264 kgs (Excl 2% Wastage))	1 Number	4	Amoxicillin Trihydrate BP Compacted	2625.00 mg.
Moxileb Oral Suspension. Amoxicillin Oral Suspension (Amoxicillin Syrup) 250 Mg /100 ml Bottle. ((Each 5ml Contains Amoxicillin Trihydrate Equivalent To 250 mg of Amoxicillin). Net Content of Import/Exempt Material Used In Export Product 1) Amoxicillin Trihydrate BP (Compacted) - 120.54 Kgs (Excl 2% Wastage).)	1 Number	5	Amoxicillin Trihydrate BP Compacted	5250.00 mg.
RA concerned may take further necessary action as per above decision of NC-III.				

Case No.	88 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001901AM26
RA File Number	05AX04001216 AM26
Licence No and Date	0511033709/07/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Naloxone Hydrochloride Injection USP, 0.4 mg /ml	1 Number	1	Naloxone Hydrochloride USP	0.44 mg/Vial

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

Case No.	89 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001904AM26
RA File Number	05AX04001205 AM26
Licence No and Date	0511033713/07/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Tobramycin Inhalation Solution, 300 mg/ 4ml	1 Number Pack	1	Tobramycin USP	315 mg./Vial
Tobramycin Inhalation Solution, 300 mg/ 5ml	1 Number Pack	2	Tobramycin USP	315 mg./Vial

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

Case No.	90 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001905AM26
RA File Number	05AX04001215 AM26
Licence No and Date	0511033716/07/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0511027509 dated 03/09/2024 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Atropine Sulphate Ophthalmic Solution USP, 1% 5 ml.	1 Number	1	Atropine Sulphate	51.00 mg.

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

Case No.	91 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001907AM26
RA File Number	03AX04001485 AM26
Licence No and Date	0311045423/07/07/2025
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents from the firm:- I. Export description is not matching with the composition given in Drug Manufacturing Licence (DML). II. Import quantity not matching with Drug Manufacturing Licence approved composition.	

Case No.	92 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001915AM26
RA File Number	03AX04001681 AM26
Licence No and Date	0311045442/07/07/2025
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Secnol (Secnidazole Sachet 2 gm) (Net content of Secnidazole IH 2 mg)	1 Number	1	Secnidazole IH	2.00 gm/Sachet

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

Case No.	93 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001917AM26
RA File Number	34AX04000306 AM26
Licence No and Date	3411006695/07/07/2025

Norms Committee Decision:

The firm was initially granted an Advance Authorisation for the export product “CIS-3-Hexenyl Salicylate” under Para 4.07 of the Handbook of Procedures (HBP). However, as per Para 4.11(b) of the Foreign Trade Policy (FTP) 2023, products falling under the category of perfume or perfumery compounds are ineligible for authorisation under Para 4.07 and are mandatorily required to be processed under Para 4.06 of the HBP.

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

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

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

Case No.	94 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001918AM26
RA File Number	34AX04000297 AM26
Licence No and Date	3411006696/07/07/2025
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “CIS-3-Hexenyl Acetate” under Para 4.07 of the Handbook of Procedures (HBP). However, as per Para 4.11(b) of the Foreign Trade Policy (FTP) 2023, products falling under the category of perfume or perfumery compounds are ineligible for authorisation under Para 4.07 and are mandatorily required to be processed under Para 4.06 of the HBP. It was observed that the firm obtained the authorisation by misdeclaring that its application was covered under the provisions of Para 4.07, and has not furnished any technical justification/information for the export product. Accordingly, the Committee found no merit in fixing the norms and decided to reject the application. The RA shall ensure that the said authorisation is regularised by recovery of applicable Customs duty along with interest. Further, the RA should also submit a report on how this authorisation was issued under Para 4.07 of HBP, to the Chairperson of the Norms Committee and to PC-4 Section, DGFT Headquarters. The RA concerned may take further necessary action in line with the above decision of the Committee.	

Case No.	95 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001920AM26
RA File Number	07AX04000553 AM26
Licence No and Date	0711014962/07/07/2025

Norms Committee Decision:

The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents:

1. Complete chemical reaction, indicating molecular weight of reactant/s and product/s with overall yield of the reaction for the export item.
2. To indicate indigenous item/s in Annexure to Appendix-4E table.

Case No.	96 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001929AM26
RA File Number	30AX04000224 AM26
Licence No and Date	3011007307/08/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MEROPENEM 500 mg Powder for Solution for Injection or Infusion (Each Vial Contains: Active Pharmaceutical Ingredients Meropenem Trihydrate equivalent to Meropenem Anhydrous)	1 Number	1	Meropenem and Sodium Carbonate (Sterile Bulk)	0.6726 gm.

...500 mg , Excipients : Anhydrous Sodium carbonate ph.Eur104 mg equivalent to 45.1mg of Sodium)				
MEROPENEM 1000 mg Powder for Solution for Injection or Infusion (Each Vial Contains: Active Pharmaceutical Ingredients Meropenem Trihydrate equivalent to Meropenem Anhydrous ...1000 mg , Excipients : Anhydrous Sodium carbonate ph.Eur ...208 mg equivalent to 90.2 mg of Sodium)	1 Number	2	Meropenem and Sodium Carbonate (Sterile Bulk)	1.345 gm.
MEROPENEM 2 gm Powder for Solution for Injection or Infusion (Each Vial Contains: Active Pharmaceutical Ingredients Meropenem Trihydrate equivalent to 2000 mg Meropenem Anhydrous Excipients : Anhydrous Sodium carbonate ph.eur 416 mg equivalent to 180.4 mg of Sodium)	1 Number	3	Meropenem and Sodium Carbonate (Sterile Bulk)	2.690 gm.

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

Case No.	97 / NC/3/MEET/May/202627/3										
Case Status	Case Approved										
Party Name	RAJASTHAN ANTIBIOTICS LTD										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026										
HQ File Number	HQRNORM APPLY 00001934AM26										
RA File Number	05AX04001195 AM26										
Licence No and Date	0511033746/08/07/2025										
Norms Committee Decision:											
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below.:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Vancomycin Hydrochloride IP/ BP/ USP (Sterile Powder)</td><td>1 kg.</td><td>1</td><td>Vancomycin HCL Non-Sterile</td><td>1.01 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Vancomycin Hydrochloride IP/ BP/ USP (Sterile Powder)	1 kg.	1	Vancomycin HCL Non-Sterile	1.01 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Vancomycin Hydrochloride IP/ BP/ USP (Sterile Powder)	1 kg.	1	Vancomycin HCL Non-Sterile	1.01 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	98 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001935AM26
RA File Number	03AX04001747 AM26
Licence No and Date	0311045467/08/07/2025
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms to facilitate the issuance of Advance Authorization by the concerned Regional Authority. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical	

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

Sl. No.	Export Product	Quantity
1	Medical Ointment & Cream("Fluorouracil Topical Solution USP 5%, 10 ml Total Nt Wt. 250 Kgs (fluo 12.50 Kgs, ede 0.13 kgs, met 0.25, gly 119.76, para 0.08 Kgs, tro 21 kgs, hyd 6.25 kg, bot 25000, drop 25000, cap 25000)")	1 Number
2	Medical Ointment & Cream (Fluorouracil Cream USP 5% 40 Gm Total Nt Wt.14000 Kgs (fluo700 Kgs,wh petro2940 kgs, pro gly 1680 Kgs, stearyl alco 2100, poly 560 Kgs, pro para 2.1 kgs, methyl 3.5 Kgs))	1 Number

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

Note:

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

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

Case No.	99 / NC/3/MEET/May/202627/3
Case Status	Case Approved

Party Name	HELLO AROMATICS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026													
HQ File Number	HQRNORM APPLY 00001946AM26													
RA File Number	05AX04001143 AM26													
Licence No and Date	0511033752/08/07/2025													
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms . After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below.:- <table border="1" data-bbox="197 807 1437 1077"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Thymol (Thymol Above 99%)</td> <td>1 kg.</td> <td>1</td> <td>M CRESOL (Meta Cresol Above 99%)</td> <td>0.818 kg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Thymol (Thymol Above 99%)	1 kg.	1	M CRESOL (Meta Cresol Above 99%)	0.818 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Thymol (Thymol Above 99%)	1 kg.	1	M CRESOL (Meta Cresol Above 99%)	0.818 kg.										

Case No.	100 / NC/3/MEET/May/202627/3			
Case Status	Case Approved			
Party Name	REYAANSH HEALTHCARE			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026			
HQ File Number	HQRNORM APPLY 00001948AM26			
RA File Number	03AX04001780 AM26			
Licence No and Date	0311045487/08/07/2025			
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below.:-				

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Fluralaner & Moxidectin Spot On 0.40 ml Tube (Each ml Contains Fluralaner 280 mg + Moxidectin 14 mg. Net Quantity of Moxidectin Consumed Including Wastages & Overages : 0.300 Kgs (Net Content of Moxidectin 0.2727 KGS))	1 Number	1	Moxidectin	5.712 mg.
Fluralaner & Moxidectin Spot On 0.90 ml Tube. (Each ml Contains Fluralaner 280 mg + Moxidectin 14 mg. Net Quantity of Moxidectin Consumed Including Wastages & Overages : 0.700 Kgs (Net Content of Moxidectin 0.6364 KGS))	1 Number	2	Moxidectin	12.852 mg.
Fluralaner & Moxidectin Spot On 1.80 ml Tube (Each ml Contains Fluralaner 280 mg + Moxidectin 14 mg. Net Quantity of Moxidectin Consumed Including Wastages & Overages : 1.300 Kgs (Net Content of Moxidectin 1.1818 KGS))	1 Number	3	Moxidectin	25.704 mg.

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

Case No.	101 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	SAGA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001952AM26

RA File Number	08AX04000582 AM26			
Licence No and Date	0811015528/08/07/2025			
Norms Committee Decision:				
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Diosmin and Hesperidin Tablets 500 mg.	1 Number	1	Diosmin	459.00 mg.
		2	Hesperidin	51.00 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	102 / NC/3/MEET/May/202627/3			
Case Status	Case Approved			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026			
HQ File Number	HQRNORM APPLY 00001953AM26			
RA File Number	07AX04000609 AM26			
Licence No and Date	0711014972/08/07/2025			
Norms Committee Decision:				
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Dicloxacillin Capsules 250 mg	1 Number	1	Dicloxacillin BP/EP/USP	Sodium	267.5 mg/250 mg capsule
Dicloxacillin Capsules 500 mg	1 Number	2	Dicloxacillin BP/EP/USP	Sodium	535.0 mg/500 mg Capsule

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

Case No.	103 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001954AM26
RA File Number	07AX04000616 AM26
Licence No and Date	0711014973/08/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ramelteon 8 mg Tablets	1 Number Tablet	1	Ramelteon	8.16 mg/Tablet

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

Case No.	104 / NC/3/MEET/May/202627/3										
Case Status	Case Approved										
Party Name	MICRO LABS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026										
HQ File Number	HQRNORM APPLY 00001955AM26										
RA File Number	07AX04000613 AM26										
Licence No and Date	0711014976/08/07/2025										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against advance authorization No. 0711014615 dated 03/06/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Phloroglucinol 160 mg OD Tablets</td><td>1 Number</td><td>1</td><td>Phloroglucinol Dihydrate BP/EP/IP/USP</td><td>163.2 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Phloroglucinol 160 mg OD Tablets	1 Number	1	Phloroglucinol Dihydrate BP/EP/IP/USP	163.2 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Phloroglucinol 160 mg OD Tablets	1 Number	1	Phloroglucinol Dihydrate BP/EP/IP/USP	163.2 mg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	105 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001978AM26
RA File Number	05AX04001234 AM26
Licence No and Date	0511033779/09/07/2025
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for	

same export product/import item in meeting No.NC/3/MEET/Feb/202526/13 dated 20/02/2026 against advance authorization No. 0511032964 dated 28/05/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Visallergol Eye Drops 0.2%, 2.5ml (Each vials of Visallergol Contains 5 mg of Olopatadine)	1 Number	1	Olopatadine HCL	5.61 mg
Oftahist Eye Drops 0.1% 5 ml (OFTHAHIST (Olopatadine Eye Solution 0.1% in 5ml Vial) (Each Vials of Oftahist contains 5mg of Olopatadine))	1 Number	2	Olopatadine HCL	5.61 mg

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

Case No.	106 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	MERIDIAN ENTERPRISES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00001998AM26
RA File Number	03AX04001810 AM26
Licence No and Date	0311045558/10/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Feb/202526/13 dated 20/02/2026 against advance authorization No. 0511032964 dated 28/05/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm,

whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dequalinium Chloride Oral Spray (Dequadin Oral Spray) 25 ML Bottle. (Each ml contains: Dequalinium Chloride 0.5 percent (net content of Input per ml=5mg, Net content per 25ml bottle = 125 mg Total net content = 3.00Kgs))	1 Number	1	Dequalinium Chloride	127.50 mg.

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

Case No.	107 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	LEE PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002005AM26
RA File Number	09AX04000022 AM26
Licence No and Date	0911010000/10/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jun/202526/5 dated 30/06/2025 against advance authorization No. 0911008677 dated 20/12/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Voriconazole	1 kg.	1	4-Chloro-6-Ethyl-5-Fluoropyrimidine	3.30 kg.
		2	Tetrahydrofura	20.50 kg.
		3	L Camphor Sulfonic Acid((R)(-)-Camphorsulphonic Acid)	1.01 kg.

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

Case No.	108 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	LA CHANDRA PHARMALAB PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002006AM26
RA File Number	08AX04000617 AM26
Licence No and Date	0811015546/10/07/2025
Norms Committee Decision:	
The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: I. Stepwise complete and balanced chemical reactions showing molecular weight and percentage of yield on molar basis. II. Copy of Technical Literature/Justification for low yield of 21% in last stage of flow-charts.	

Case No.	109 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002020AM26

RA File Number	03AX04001789 AM26			
Licence No and Date	0311045608/11/07/2025			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jun/202526/5 dated 30/06/2025 against advance authorization No. 0911008677 dated 20/12/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Artemether	1 kg.	1	Artemisinin	1.04 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	110 / NC/3/MEET/May/202627/3			
Case Status	Case Approved			
Party Name	OPTIMUS DRUGS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026			
HQ File Number	HQRNORM APPLY 00002045AM26			
RA File Number	09AX04000384 AM26			
Licence No and Date	0911010015/14/07/2025			
Norms Committee Decision:				
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Tert-Butyl 2-Methyl-3-Oxo-3a-Benzyl-2H-4, 5, 6, 7, 3a-Pentahydro-5-Azaindazole-5-Carboxylate	1 kg.	1	1-Tert-Butyl 3-Methyl 4-Oxo Piperidine-1,3-Dicarboxylate	0.979 kg.
		2	Benzyl Bromide	0.68 kg.
		3	Tetra Hydro Furan (THF)	3.06 kg.
		4	N-Heptane	7.83 kg.
		5	Potassium Carbonate [K2CO3]	1.27 kg.
		6	Acetic Acid	0.225 kg.
		7	2-Methyl THF	5.60 kg.
		8	MMH 80% Solution	0.215 kg.
		9	Sodium Bicarbonate [NAHCO3]	0.39 kg.

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

Case No.	111 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002059AM26
RA File Number	08AX04000625 AM26
Licence No and Date	0811015572/14/07/2025
Norms Committee Decision:	

The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents:-

1. Drug Manufacturing Licence (DML) for export item No.3 and 4 are not given.
2. Import quantity applied for export item No. 3 and 4 are not matching with composition shown in export description.
3. Firm may be advised to get their Advance Authorisation amended with all corrections.

Case No.	112 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002062AM26
RA File Number	03AX04001851 AM26
Licence No and Date	0311045646/14/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/feb/202526/13 dated 20/02/2026 against advance authorization No. 031144099 dated 22/05/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Idezar 150 mg Tablets 28 S (Irbesartan Tablets 150 Mg 28 S) ((45,525 Boxes X 28 Tablets per Boxes = 12,74,700 Tablets) (Total Weight of Export Product = 191.205 Kgs) (Exempts imported input / material weight inclusive of wastage = 200.440 Kgs))	1 Number	1	Irbesartan Ph. Eur	153.0 mg.

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

Case No.	113 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002063AM26
RA File Number	03AX04001854 AM26
Licence No and Date	0311045647/14/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against advance authorization No. 0311045097 dated 25/06/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxycycline Hyclate DR Tablets USP 100 mg , 100 S US((8,250 Bottles X 100 Per Bottles = 8,25,000 Tablets) (Total Weight of Export Product = 82.500 Kgs) (Exempts imported input / material weight inclusive of wastage = 105.262 Kgs))	1 Number Tablet	1	Doxycycline Hyclate USP	117.72 mg.

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

Case No.	114 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002064AM26
RA File Number	03AX04001853 AM26
Licence No and Date	0311045649/15/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxycycline Tablets, USP 100 MG 50 S ((1,40,000 Bottles X 50 Per Bottles = 70,00,000 Tablets) (Total Weight of Export Product = 700.000 Kgs) (Exempts imported input / material weight inclusive of wastage = 757.120 Kgs))	1 Number	1	Doxycycline USP (Monohydrate)	109.68 mg/100 mg Tablet
Doxycycline Tablets, USP 100 MG 500 S ((16,800 Bottles X 500 Per Bottles = 84,00,000 Tablets) (Total Weight of Export Product = 840.000 Kgs) (Exempts imported input /material weight inclusive of wastage = 908.544 Kgs))	1 Number	2	Doxycycline USP (Monohydrate)	109.68 mg/100 mg Tablet

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

Case No.	115 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002104AM26
RA File Number	34AX04000324 AM26
Licence No and Date	3411006740/16/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2 Ethyl Hexyl Nitrate	1 kg.	1	Ethyl Hexanol	0.748 kg.
		2	Nitric Acid 98 Percent	0.386 kg.

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

Case No.	116 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	SAPTAGIR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002111AM26
RA File Number	09AX04000337 AM26

Licence No and Date	0911010039/16/07/2025
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “Ambrogir” 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.	117 / NC/3/MEET/May/202627/3				
Case Status	Case Approved				
Party Name	MACLEODS PHARMACEUTICALS LTD				
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026				
HQ File Number	HQRNORM APPLY 00002128AM26				
RA File Number	03AX04001857 AM26				
Licence No and Date	0311045715/17/07/2025				
Norms Committee Decision:					
The Committee examined the request of the firm for fixation of ad-hoc norms . After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below.:-					

LEVOFLOXACIN 500 MG TABLET (each tablet contain Levofloxacin Hemihydrate equivalent to Levofloxacin 500mg) ((1 tablet contain consumed raw material 522.75 mg Levo Hemihydrate made from 547.7 mg 9,10-Difluoro- 2,3-Dihydro-3-Methyl-7-Oxo- (3s)-7h- Pyrido (1,2,3-De)1,4- Benzoxazine-6-Carboxylic Acid (Levo Q Acid) and 438.215 mg 1- Methylpiperazine (N-Methylpiperazine))	1 Number	1	9,10-Difluoro-2,3- Dihydro-3-Methyl-7- Oxo-(3s)-7h- Pyrido(1,2,3-De)1,4- Benzoxazine-6- Carboxylic Acid (Levofloxacin Q Acid) (KSM of Levofloxacin Hemihydrate)	0.447 gm.
		2	1-Methylpiperazine (N- Methylpiperazine) (Intermediate of Levofloxacin Hemihydrate)	0.226 gm.

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

Case No.	118 / NC/3/MEET/May/202627/3			
Case Status	Case Approved			
Party Name	APITORIA PHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026			
HQ File Number	HQRNORM APPLY 00002132AM26			
RA File Number	09AX04000394 AM26			
Licence No and Date	0911010042/17/07/2025			
Norms Committee Decision:				
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below.:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Rivaroxaban	1 kg.	1	Diethyl chlorophosphate (or) Diethyl phosphorochloridate	0.620 kg.
		2	Methanol (Methyl Alcohol)	5.50 kg.
		3	Activated Carbon (Carbon Enoanticromos)	0.0322 kg.

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

Case No.	119 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	DEVI PHARMATECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002135AM26
RA File Number	09AX04000330 AM26
Licence No and Date	0911010048/17/07/2025
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: A balanced chemical reaction, indicating molecular weight of reactant/s and product/s with overall yield of the reaction for the export item.	

Case No.	120 / NC/3/MEET/May/202627/3
Case Status	Case Rejected
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002152AM26
RA File Number	05AX04001341 AM26
Licence No and Date	0511033928/17/07/2025
Norms Committee Decision: The firm was initially granted an Advance Authorisation for the export product “<i>Linalyl Acetate Refined</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.	121 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002156AM26
RA File Number	08AX04000663 AM26
Licence No and Date	0811015606/17/07/2025
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No. 0811010749 dated 13/02/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm,	

whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Lapox ARD-12 (Reactive Diluent) (4-ter-Butylphenol glycidyl ether)	1 kg.	1	Para Tertiary Butyl Phenol	0.54 kg.
		2	pichlorohydrin	0.48 kg.

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

Case No.	122 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002166AM26
RA File Number	03AX04001946 AM26
Licence No and Date	0311045745/18/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No. 0311004323 dated 04/06/2021, 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.
Bleomycin Sulfate for Injection 15000 IU (Lyophilised)	1 Number	1	Bleomycin Sulfate PH EUR	10.00 mg.

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

Case No.	123 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002169AM26
RA File Number	30AX04000269 AM26
Licence No and Date	3011007397/18/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Feb/202526/13 dated 20/02/2026 against Advance Authorization No.3011007033 dated 27/05/2025 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ceftriaxone powder for solution for injection 500 mg (Each vial contains: Ceftriaxone Sodium equivalent to ceftriaxone...500 mg)	1 Number	1	Ceftriaxone Sodium Sterile	580 mg.
Ceftriaxone powder for solution for injection 1000 mg (Each vial contains: Ceftriaxone sodium Equivalent to ceftriaxone..1000 mg)	1 Number	2	Ceftriaxone Sodium Sterile	1.16 gm.
Ceftriaxone powder for solution for injection 2000 mg (Each vial contains: Ceftriaxone sodium equivalent to ceftriaxone..2000 mg)	1 Number	3	Ceftriaxone Sodium Sterile	2.32 gm.

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

Case No.	124 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002170AM26
RA File Number	30AX04000270 AM26
Licence No and Date	3011007398/18/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Oct/202526/9 dated 14/10/2025 against Advance Authorization No. 3011006632 dated 05/03/2025, 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.
Topotecan Hydrochloride for Injection 4.0 mg (Each vial contains: Topotecan Hydrochloride Equivalent to Topotecan4 mg)	1 Number	1	Topotecan Hydrochloride	4.78 mg/Vial

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

Case No.	125 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	KLJ PLASTICIZERS LIMITED.

Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026																
HQ File Number	HQRNORM APPLY 00002173AM26																
RA File Number	05AX04001340 AM26																
Licence No and Date	0511033947/18/07/2025																
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Feb/202526/13 dated 20/02/2026 against Advance Authorization No. 0511032197 dated 29/04/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="196 805 1428 1106"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Di-Ethyl Maleate (DEM)</td> <td rowspan="2">1 kg.</td> <td>1</td> <td>Maleic Anhydride</td> <td>0.67 kg.</td> </tr> <tr> <td>2</td> <td>Denatured Ethyl Alcohol</td> <td>0.65 kg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Di-Ethyl Maleate (DEM)	1 kg.	1	Maleic Anhydride	0.67 kg.	2	Denatured Ethyl Alcohol	0.65 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Di-Ethyl Maleate (DEM)	1 kg.	1	Maleic Anhydride	0.67 kg.													
		2	Denatured Ethyl Alcohol	0.65 kg.													

Case No.	126 / NC/3/MEET/May/202627/3			
Case Status	Case Approved			
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026			
HQ File Number	HQRNORM APPLY 00002191AM26			
RA File Number	03AX04001883 AM26			
Licence No and Date	0311045792/21/07/2025			
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jul/202526/6 dated 31/07/2025 against Advance Authorization No. 0311039942 dated 29/12/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm,				

whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Azithromycin Dihydrate	1 kg.	1	Azithromycin Amine	0.9434 kg.

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

Case No.	127 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002198AM26
RA File Number	08AX04000640 AM26
Licence No and Date	0811015631/21/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jul/202526/6 dated 31/07/2025 against Advance Authorization No. 0811013766 dated 09/01/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Esmolol Hydrochloride in Sodium Chloride Injection 2,500 mg/250 ml (10 mg/ml)	1 Number	1	Esmolol	2625 mg.
Esmolol Hydrochloride in Sodium	1 Number	2	Esmolol	2100 mg.

Chloride Injection [Double Strength] 2,000 mg/100 ml (20 mg/ml)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	128 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002206AM26
RA File Number	03AX04001970 AM26
Licence No and Date	0311045808/21/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Chloramphenicol Eye Drops 10 Ml ((Each Vial Contains Chloramphenicol Micronized 0.050 gm Net Wt of Bulk Drug is 16 Kgs))	1 Number	1	Chloramphenicol Micronized (API)	51.00 mg.

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

Case No.	129 / NC/3/MEET/May/202627/3										
Case Status	Case Approved										
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026										
HQ File Number	HQRNORM APPLY 00002216AM26										
RA File Number	03AX04001932 AM26										
Licence No and Date	0311045821/21/07/2025										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against Advance Authorization No. 0311045089 dated 25/06/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Artemether</td><td>1 kg.</td><td>1</td><td>Artemisinin</td><td>1.04 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Artemether	1 kg.	1	Artemisinin	1.04 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Artemether	1 kg.	1	Artemisinin	1.04 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	130 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002217AM26
RA File Number	03AX04001986 AM26
Licence No and Date	0311045822/21/07/2025
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against Advance Authorization No. 9311944919 dated 19/06/2025, it was decided to fix ad-hoc	

norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Vibegron (Obgemsa / Gemtesa) Tablets 75 mg	1 Number	1	Vibegron	76.50 mg.

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

Case No.	131 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	STERMONE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002254AM26
RA File Number	34AX04000381 AM26
Licence No and Date	3411006762/23/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Betamethasone Dipropionate BP/EP/USP	1 kg.	1	Betamethasone 17-Propionate	0.94 kg.

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

Case No.	132 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	STERMONE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002256AM26
RA File Number	34AX04000382 AM26
Licence No and Date	3411006764/23/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Clobetasol Propionate BP/EP/USP	1 kg.	1	Betamethasone 17-Propionate	1.08 kg.

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

Case No.	133 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	DR.ACHARYA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002260AM26
RA File Number	03AX04002004 AM26
Licence No and	0311045883/23/07/2025

Date	
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. To give yield of the reaction with justification. 2. A balanced chemical reaction indicating molecular weight of tetrahydrofuran (THF). 3. Stoichiometric material balance of the reaction on molar basis.	

Case No.	134 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	SHREE BANKEY BEHARI LAL AROMATICS
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002290AM26
RA File Number	05AX04001415 AM26
Licence No and Date	0511034080/24/07/2025
Norms Committee Decision: The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents: 1. Certificate of Analysis (CoA) of import item from foreign supplier indicating percentage content of Eucalyptol in import.	

Case No.	135 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002291AM26
RA File Number	05AX04001451 AM26

Licence No and Date	0511034082/24/07/2025				
Norms Committee Decision:					
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.
Proparacaine Hydrochloride Ophthalmic Solution USP 0.5%, 15 ml.		1 Number	1	Proparacaine Hydrochloride USP	76.5 mg/Vial
RA concerned may take further necessary action as per above decision of NC.					

Case No.	136 / NC/3/MEET/May/202627/3				
Case Status	Case Approved				
Party Name	APITORIA PHARMA PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026				
HQ File Number	HQRNORM APPLY 00002301AM26				
RA File Number	09AX04000422 AM26				
Licence No and Date	0911010084/25/07/2025				
Norms Committee Decision:					
The Committee examined the request of the firm for fixation of ad-hoc norms . After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.

Cefalexin Monohydrate	1 kg.	1	7-Amino Des-Acetoxy Cephalosporanic Acid (7-ADCA)	0.6528 kg.
		2	Carbon Enoanticromos (Activated Carbon)	0.019 kg.
		3	D-phenyl glycine methyl ester Hydrochloride	0.696 kg.
		4	Penicillin G Amidase	0.0045 kg.
		5	Methylene Chloride	0.1501 kg.
		6	Acetone	0.1046 kg.

Note:

- i. Revision of SION A-114 as per above proposed norms.
- ii. Suspension of SION A-116 for revision from Penicillin G which is raw material for 6-ADCA.

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

Case No.	137 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002346AM26
RA File Number	07AX04000756 AM26
Licence No and Date	0711015186/28/07/2025
Norms Committee Decision:	

The committee considered the case as per the agenda and after examination, it was observed that the firm has not furnished the requisite technical details as prescribed in Annexure to Appendix 4E. After detailed deliberations and in view of the recommendations of the Technical Authority, the Committee decided to ask the firm to furnish the following documents:-

1. A balanced chemical reaction, indicating molecular weight of reactant/s and product/s with yield of the reaction for the manufacture of export item.
2. To indicate indigenous item/s in Annexure to Appendix-4E.

Case No.	138 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	GANPATI PHARMA
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002350AM26
RA File Number	13AX04000137 AM26
Licence No and Date	1311004092/28/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tablet Perphenazine 2 mg	1 Number	1	Perphenazine CAS: 58-39-9)	2.04 mg/Tablet
Tablet Perphenazine 4 mg	1 Number	2	Perphenazine CAS: 58-39-9)	4.08 mg/Tablet
Tablet Perphenazine 8 mg	1 Number	3	Perphenazine CAS: 58-39-9)	8.16 mg/Tablet

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

Case No.	139 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ZENITH DYEINTERMEDIATES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00003608AM26
RA File Number	NA
Licence No and Date	0311045978/28/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aur/202425/8 dated 28/08/2024 against Advance Authorization No. 0311033314 dated 24/04/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NAS-5((2-DIAZO-1-NAPTHOL-5-SULFONIC ACID, SODIUM SALT))	1 kg.	1	Tobias Acid (Purity 97%)	0.70 kg.

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

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

Case No.	140 / NC/3/MEET/May/202627/3
Case Status	Case Approved

Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026													
HQ File Number	HQRNORM APPLY 00002367AM26													
RA File Number	09AX04000413 AM26													
Licence No and Date	0911010093/29/07/2025													
Norms Committee Decision: The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less, as per the details indicated below:- <table border="1" data-bbox="196 802 1428 1047"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Paracetamol & Caffeine 500/65 mg Tablets</td> <td>1 Number</td> <td>1</td> <td>Caffeine Anhydrous Ph.Eur CEP</td> <td>66.3 mg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Paracetamol & Caffeine 500/65 mg Tablets	1 Number	1	Caffeine Anhydrous Ph.Eur CEP	66.3 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Paracetamol & Caffeine 500/65 mg Tablets	1 Number	1	Caffeine Anhydrous Ph.Eur CEP	66.3 mg.										

Case No.	141 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002383AM26
RA File Number	09AX04000400 AM26
Licence No and Date	0911010105/29/07/2025
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against Advance Authorization No. 0911009916 dated 26/06/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

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

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

Case No.	142 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002384AM26
RA File Number	03AX04002160 AM26
Licence No and Date	0311046034/29/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Lumefantrine	1 kg.	1	9H Fluorene	0.814 kg.
		2	Di N Butylamine	0.390 kg.
		3	Sodium Borohydride	0.040 kg.
		4	Para Chloro Benzaldehyde	0.336 kg.
		5	Di Methyl Formamide	0.555 kg.

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

Case No.	143 / NC/3/MEET/May/202627/3
Case Status	Case Approved

Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002392AM26
RA File Number	03AX04002128 AM26
Licence No and Date	0311046045/30/07/2025

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NEODOX GOLD WSP (pack Size 1 Kgs Jar) Each gram contains: Doxycycline Hyclate BP/EP/USP 100 mg, (Neomycin Sulfate BP/EP/USP 100 mg Net wt. Doxycycline Hyclate BP/EP/USP 500.00 Kgs Net wt. Neomycin Sulfate BP/EP/USP 500.00 Kgs)	1 Number	1	Doxycycline Hyclate BP/EP/USP	101.00 gm.
		3	Neomycin Sulfate BP/EP/USP	101.00 gm.
NEODOX -GOLD WSP (pack Size 100 Gms Sachet) Each gram contains: Doxycycline Hyclate BP/EP/USP 100 mg, (Neomycin Sulfate BP/EP/USP 100 mg Net wt. Doxycycline Hyclate BP/EP/USP 250.00 Kgs Net wt. Neomycin Sulfate BP/EP/USP	1 Number	2	Doxycycline Hyclate BP/EP/USP	10.10 gm.
		4	Neomycin Sulfate BP/EP/USP	10.10 gm.

250.00 Kgs)

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

Case No.	144 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002395AM26
RA File Number	08AX04000747 AM26
Licence No and Date	0811015732/30/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Sep/202526/8 dated 17/09/2025 against Advance Authorization No. 0811013820 dated 16/01/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SEVELAMER CARBONATE FOR ORAL SUSPENSION 2.4 G (SEVELAMER CARBONATE 2.4 GRAM POWDER FOR ORAL SUSPENSION SACHETS) (EACH PACKETS/SACHETS CONTAINS : SEVELAMER CARBONATE FOR ORAL SUSPENSION 2.4 Gram NET CONTENT OF SEVELAMER CARBONATE SHOULD NOT BE LESS THAN 792.00 KG IN EXPORT ITEM)	330000 Numbers	1	Sevelamer Carbonate	831.60 kg.

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

Case No.	145 / NC/3/MEET/May/202627/3
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002411AM26
RA File Number	07AX04000792 AM26
Licence No and Date	0711015226/30/07/2025
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant information / documents from the firm:	

Case No.	146 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002417AM26
RA File Number	03AX04002124 AM26
Licence No and Date	0311046087/31/07/2025
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against Advance Authorization No. 0311044919 dated 19/06/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Vibegron (Gemtesa/ Obgemsa) Tablets 75 mg	1 Number	1	Vibegron	76.50 mg.

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

Case No.	147 / NC/3/MEET/May/202627/3													
Case Status	Case Approved													
Party Name	ALCHEMIE FINECHEM PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026													
HQ File Number	HQRNORM APPLY 00002421AM26													
RA File Number	03AX04001481 AM26													
Licence No and Date	0311046100/31/07/2025													
Norms Committee Decision:														
The Committee examined the request of the firm for fixation of ad-hoc norms. After due deliberation, the Committee decided to fix the ad-hoc norms on the basis of inputs received from the Technical Authority or as applied for by the firm, whichever is less , as per the details indicated below.:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">AF131-1(NMPT) (AF131-1 (N,Methyl Para Toluidine))</td><td rowspan="2">1 kg.</td><td>1</td><td>Para Toluidine</td><td>0.956 kg.</td></tr><tr><td>2</td><td>Methanol</td><td>0.286 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	AF131-1(NMPT) (AF131-1 (N,Methyl Para Toluidine))	1 kg.	1	Para Toluidine	0.956 kg.	2	Methanol	0.286 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
AF131-1(NMPT) (AF131-1 (N,Methyl Para Toluidine))	1 kg.	1	Para Toluidine	0.956 kg.										
		2	Methanol	0.286 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	148 / NC/3/MEET/May/202627/3
Case Status	Case Approved
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202627/ 3 and 26/05/2026
HQ File Number	HQRNORM APPLY 00002426AM26
RA File Number	09AX04000399 AM26
Licence No and Date	0911010140/31/07/2025

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202627/1 dated 07/04/2026 against Advance Authorisation No.0911009916 dated 26/06/2025, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Liraglutide Injection 18 mg/3 ml (6 mg/mL) 1x3's ((Each 3 ml contains Liraglutide 18 mg) Fill Volume- 3.3 ml)	1 Number	1	Liraglutide (API- (Water Content - upto 6.4%, Sodium Ion- 1.8%)=8.20%)	19.8 mg/ Vial
		2	3.0 mL Pre - Crimped Glass Siliconized Cartridge (Cartridge EZ-Fill Nexa VB 3mL)	Relevant, as per Packing Policy & General Notes.
		3	BD Vystra Disposable Pen Body Subassembly with Purple Colour Dose Button (VYSTRA BSA FR PL 284C BTN 2685C 50IU)	Relevant, as per Packing Policy & General Notes.

		4	BD Vystra Disposable Pen Printed Cartridge Holder (VYSTRACARTRIDGE HOLDER PRINTED 0.6-15)	Relevant, as per Packing Policy & General Notes.
		5	BD Vystra Disposable Pen Cap (VYSTRACAP PL MODERN 284C)	Relevant, as per Packing Policy & General Notes.

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