



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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III**MEETING No.** NC/3/MEET/Nov/202425/10**DATED:** 22/11/2024Please Note

- I. For information of exporters, Norms Committee - III handles all cases pertaining to fixation/ratification of norms for Export Products falling under ITC (HS) Chapter 29, 30 .Communications in respect of cases/pertaining to NC- III may be sent to email address: nc3.dgft@nic.in
- II. The Norms Committee has taken decision only with respect to technical aspect/wastage norms. While redeeming the applications, RAs should check that the applicant has fulfilled all requirements as prescribed in policy/procedure including those in Policy Circulars issued from time to time or any other provisions under FTP/HBP for EODC.
- III. Wherever the Committee has fixed Norms, the concerned RA may ensure that AA is issued on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less.
- IV. RAs shall ensure compliance of SION, General Notes and Chapter Notes wherever applicable.
- V. RAs shall also ensure that authorisation 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 of the provisions of Para 4.12 of FTP, Para 4.16; Para 4.21; and Pra 4.51 of HBP shall be made.

Meeting No. NC/3/MEET/Nov/202425/10 dated 22/11/2024 of Norms Committee - III for the year 2024-25 was held on 22/11/2024 under the Chairmanship of Shri Rakesh Kumar, Additional DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2023.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	Shri Rakesh Kumar, Addl. DGFT	DGFT(HQ)

2	Shri Raman Kumar, Deputy DGFT	DGFT(HQ)
3	Shri Dinesh Narain Mathur, Technical Expert	Consultant (Pharma)
4	Shri Shaish Kumar, Technical Expert	Consultant (Chemical)
5	Shri Nand Lal, Technical Expert	Consultant (Chemical)
6	Shri Uttam Dey Sarkar, ASO	DGFT (HQ)

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	ADSI LA ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00002270AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- DML for 718 mg. Fish Oil Capsule.	

Case No.	2 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	TROI KAA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00002512AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of DML showing approved composition of export item. 2. Master-Batch Formula shoing net content of all inputs. 3. Export quantity in numbers of injections.	

Case No.	3 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	VINDHYA ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00002820AM25

RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Complete technical details as per Annexure to Appendix-4.	

Case No.	4 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00003140AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

AZITHROMYCIN USP - NET WT. 530.382 KGS))				
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.	5 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00003176AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
Decision: The committee considered the case as per agenda and it was decided to fix ad-hoc norms as per SION A-1294.	

Case No.	6 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	018205000499AM20
RA File Number	039404000373 AM20
Licence No and Date	0310830887/07/08/2019
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	7 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00004443AM23
RA File Number	34AX04000759 AM23
Licence No and Date	3411003012/18/11/2022
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it has been observed that the firm has still not furnished the following documents/information as sought by the committee in its meeting held on 24/03.2023. Therefore, it was decided to give last change to the firm to furnish the said documents/information:- i. Complete chemical reactions and molecular weights along with stage wise percentage yields on molar basis. ii. Requirement and recovery of solvent at each step.	

Case No.	8 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024																				
HQ File Number	HQRNORM APPLY 00004891AM23																				
RA File Number	05AX04002651 AM23																				
Licence No and Date	0511016260/08/12/2022																				
Norms Committee Decision: 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/202324/20 dated 18/01/2024 against advance authorization No. 0511018497 dated 25/04/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table 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>Ofloxacin Otic Solution, 5ml (Having net content of 6.63 kg of Bulk Drug)</td> <td>1 Number</td> <td>1</td> <td>OFLOXACIN USP</td> <td>15.30 mg.</td> </tr> <tr> <td>Ofloxacin Otic Solution, 10ml (Having net content of 6.63 kg of Bulk Drug)</td> <td>1 Number</td> <td>2</td> <td>OFLOXACIN USP</td> <td>30.60 mg.</td> </tr> <tr> <td>Ofloxacin Ophthalmic Solution, USP, 5ml (Having net content of 9.69 kg of Bulk Drug)</td> <td>1 Number</td> <td>3</td> <td>OFLOXACIN USP</td> <td>15.30 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.	Ofloxacin Otic Solution, 5ml (Having net content of 6.63 kg of Bulk Drug)	1 Number	1	OFLOXACIN USP	15.30 mg.	Ofloxacin Otic Solution, 10ml (Having net content of 6.63 kg of Bulk Drug)	1 Number	2	OFLOXACIN USP	30.60 mg.	Ofloxacin Ophthalmic Solution, USP, 5ml (Having net content of 9.69 kg of Bulk Drug)	1 Number	3	OFLOXACIN USP	15.30 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																	
Ofloxacin Otic Solution, 5ml (Having net content of 6.63 kg of Bulk Drug)	1 Number	1	OFLOXACIN USP	15.30 mg.																	
Ofloxacin Otic Solution, 10ml (Having net content of 6.63 kg of Bulk Drug)	1 Number	2	OFLOXACIN USP	30.60 mg.																	
Ofloxacin Ophthalmic Solution, USP, 5ml (Having net content of 9.69 kg of Bulk Drug)	1 Number	3	OFLOXACIN USP	15.30 mg.																	

Case No.	9 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	DELTA FINOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00004995AM23
RA File Number	03AX04004505 AM23
Licence No and Date	0311019991/15/12/2022

Norms Committee Decision:

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

1. To give balance chemical reaction indicating molecular weight of both reactants and products.
2. To give the correct formula of 2 Amino Pyridine and accordingly, to correct the chemical reaction at B1 and 2 of Technical details.
3. Current production consumption data duly certified by Chartered Accountant.

Case No.	10 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	MEGHMANI INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00005857AM23
RA File Number	08AX04001681 AM23
Licence No and Date	0811007072/21/01/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,2,4 TRIAZINONE	1 kg.	1	Dichloropinacoline	1.0 kg.
		2	Thiocarbahydrazide	0.569 kg.

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

Case No.	11 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00005897AM23
RA File Number	34AX04000965 AM23
Licence No and Date	3411003278/24/01/2023
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Copy of Master-Batch Formula showing net content of all inputs in the export product.	

Case No.	12 / NC/3/MEET/Nov/202425/10													
Case Status	Case Approved													
Party Name	SANJIVANI PHARMA													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024													
HQ File Number	HQRNORM APPLY 00005920AM23													
RA File Number	34AX04000896 AM23													
Licence No and Date	3411003302/25/01/2023													
Norms Committee Decision:														
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>METHYL COBALAMINE</td><td>1 kg.</td><td>1</td><td>CYNOCOBALAMINE</td><td>0.869 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	METHYL COBALAMINE	1 kg.	1	CYNOCOBALAMINE	0.869 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
METHYL COBALAMINE	1 kg.	1	CYNOCOBALAMINE	0.869 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	13 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024

and Date	
HQ File Number	HQRNORM APPLY 00005943AM23
RA File Number	09AX04000960 AM23
Licence No and Date	0911004371/27/01/2023

Norms Committee Decision:

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/202324/20 dated 18/01/2024** against advance authorization **No. 0911003411 dated 27/07/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Piperacillin Hydrate	1 kg.	1	6-Amino Penicillanic Acid (6-APA)	0.5139 kg.
		2	Carbon Enoanticromos (Activated Carbon)	0.063 kg.
		3	D(-) Alpha Phenyl Glycine Base (PG Base)	0.4015 kg.
		4	Isopropyl Alcohol (IPA)	0.320 kg.
		5	Methanol (Methyl Alcohol)	0.778 kg.
		6	Methylene Chloride	2.810 kg.
		7	Pivaloyl Chloride	0.3058 kg.
		8	Potassium Carbonate (Anhydrous)	0.1838 kg.
		9	4-Ethyl-2, 3 Dioxo Piperazine (EDP)	0.4113 kg.
		10	Trimethyl Chlorosilane	0.3778 kg.
		11	Triphosgene	0.3154 kg.

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

Case No.	14 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00005991AM23
RA File Number	08AX04001832 AM23
Licence No and Date	0811007126/31/01/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ALENDRONATE SODIUM TABLETS 5 MG(EACH UNCOATED TABLET CONTAINS: ALENDRONATE SODIUM TRIHYDRATE EP 6.53 MG EQ. TO ALENDRONIC ACID 5 MG)	1 Number Tablet	1	ALENDRONATE SODIUM TRIHYDRATE EP / BP / IP / USP / PH. EUR.	6.661 mg.
ALENDRONATE SODIUM TABLETS 10 MG(EACH UNCOATED TABLET CONTAINS: ALENDRONATE SODIUM TRIHYDRATE EP 13.05 MG EQ. TO ALENDRONIC ACID 10 MG)	1 Number Tablet	2	ALENDRONATE SODIUM TRIHYDRATE EP / BP / IP / USP / PH. EUR.	13.311 mg.
ALENDRONATE SODIUM TABLETS 70 MG(EACH UNCOATED TABLET CONTAINS: ALENDRONATE SODIUM TRIHYDRATE EP	1 Number Tablet	3	ALENDRONATE SODIUM TRIHYDRATE EP / BP / IP / USP / PH. EUR.	93.197 mg.

91.37 MG EQ. TO ALENDRONIC ACID 70 MG [IN WHICH ACTIVE INGREDIENT ALENDRONATE SODIUM TRIHYDRATE USED IS 77.673 KGS.])				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	15 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00005992AM23
RA File Number	05AX04003132 AM23
Licence No and Date	0511017077/31/01/2023

Norms Committee Decision:

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/202425/7 dated 06/08/2024** against **Hqr. File No. HQRNORMAPPLY00001755AM25**, 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.
Latanoprost and Timolol Maleate Ophthalmic Solution 0.005% w/v/0.5% w/v, 2.5ml(Each ml contains Latanoprost 0.05 mg (Equivalent to 6.250 Gram of Bulk Drug) and Timolol Maleate 6.83 mg = Timolol 5 mg (Equivalent to 853.750	1 Number	1	TIMOLOL MALEATE	17.94 mg.
		2	LATANOPROST	0.1275 mg.

Gram of Bulk Drug))				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	16 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00006001AM23
RA File Number	03AX04005245 AM23
Licence No and Date	0311021062/31/01/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
AZELASTINE EYE DROPS 8 ML((NET CONTAINS AZELASTINE HYDROCHLODRIDE 0.5 MG PER VIAL OF 8 ML NET WT OF BULK DRUG IS 144 GRAMS))	1 Vial	1	AZELASTINE HYDROCHLORIDE	0.51 mg/vial

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

Case No.	17 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved

Party Name	FRESENIUS KABI ONCOLOGY LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024										
HQ File Number	HQRNORM APPLY 00006022AM23										
RA File Number	05AX04003065 AM23										
Licence No and Date	0511017109/01/02/2023										
Norms Committee Decision: 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/202324/7 dated 06/08/2024 against advance authorization No. 0511013693 dated 11/07/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="196 789 1428 1061"> <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>Ropivacaine Hydrochloride Anhydrous (API)</td><td>1 kg</td><td>1</td><td>(S)-2',6' Pipecoloxylidide OR (S)-N-(2,6-dimethyl phenyl-2-piperidinecarboxamide)</td><td>0.923 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.	Ropivacaine Hydrochloride Anhydrous (API)	1 kg	1	(S)-2',6' Pipecoloxylidide OR (S)-N-(2,6-dimethyl phenyl-2-piperidinecarboxamide)	0.923 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Ropivacaine Hydrochloride Anhydrous (API)	1 kg	1	(S)-2',6' Pipecoloxylidide OR (S)-N-(2,6-dimethyl phenyl-2-piperidinecarboxamide)	0.923 kg.							

Case No.	18 / NC/3/MEET/Nov/202425/10					
Case Status	Case Approved					
Party Name	CLAROID PHARMACEUTICALS PRIVATE LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024					
HQ File Number	HQRNORM APPLY 00006027AM23					
RA File Number	08AX04001720 AM23					
Licence No and Date	0811007147/01/02/2023					
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="196 1875 1428 1973"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.		

ERYTHROMYCIN 500 MG (85,00,000 TABLETS) (ERYTHROMYCIN STEARATE 706 MG IS EQUILENT TO ERYTHROMYCIN 500 MG)	1 Number	1	ERYTHROMYCINSTEARATE	706 mg/Tablet
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Note:

1. NC also decided to revise the SION A-222 for above products based on revised ad-hoc norms.
2. For other variation of export item, norms may be worked-out on pro-rata basis.

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

Case No.	19 / NC/3/MEET/Nov/202425/10				
Case Status	Case Approved				
Party Name	CONNEX PHARMA PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024				
HQ File Number	HQRNORM APPLY 00001735AM24				
RA File Number	26AX04000033 AM24				
Licence No and Date	2611000980/16/06/2023				
Norms Committee Decision:					
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					

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

Case No.	20 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	KAVALIFE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00005806AM24
RA File Number	07AX04000908 AM24
Licence No and Date	0711009260/21/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Natural Caffeine Anhydrous (NLT 98.5%)	1 kg.	1	Natural Caffeine Powder 98.5%	1.0 kg.

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

Case No.	21 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	AKUMS DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00006789AM24
RA File Number	05AX04002288 AM24
Licence No and Date	0511022010/09/11/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
UTERONE 200 (Progesterone BP 200 mg)(Each soft gelatin capsule contains Progesterone BP 200 mg (Naturally Micronized) Excipients (Methylparaben BP & Propylparaben BP used as preservative))	1 Number	1	PROGESTERONE MICRONISED (STANDARD:BP)	204 mg.
PROSTAR 200 (Progesterone BP 200 mg)	1 Number	2	PROGESTERONE MICRONISED (STANDARD:BP)	204 mg.

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

Case No.	22 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008450AM24
RA File Number	03AX04005000 AM24
Licence No and Date	0311030997/09/02/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Hexoral Tabs Express/ Hexoraletten N Lozenges Sugar Free. Each Lozenge contains (i) Chlorhexidine Dihydrochloride - 5 mg((ii) Benzocaine - 1.50 mg (iii) Isomalt - 2289.65 mg.	1 Number	1	Chlorhexidine Dihydrochloride	5.1 mg.
		2	Benzocaine	1.53 mg.
		3	Isomalt	2289.65 mg

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

Case No.	23 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008464AM24
RA File Number	05AX04003559 AM24
Licence No and Date	0511023876/09/02/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Apr/202425/1 dated 10/04/2024** against advance authorization **No.0311008815 dated 24/11/2021** , 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.
2-Acetoacetoxy Ethyl Methacrylate	1 kg.	1	2-Hydroxy Ethyl Methacrylate	0.640 kg.
		2	Glacial Acetic Acid	0.755 kg.

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

Case No.	24 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	ELPPE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008471AM24
RA File Number	03AX04004959 AM24
Licence No and Date	0311031032/09/02/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical name of IE AT32P & PYRIDOXAL 5 FOSFAT and to enclose catalogue and to indicate calculation of requirement the chemicals. 2. To indicate indigenous item in Appendix-4E, to use in the process. 3. The commercial value of by-product Acetone supported by Invoices. 4. End use of export item and percentage yield of the reaction with justification, giving stoichiometric material balance on molar basis.	

Case No.	25 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	SMILAX LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008518AM24
RA File Number	09AX04000984 AM24
Licence No and Date	0911006732/12/02/2024
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Norfloxacin	1 kg.	1	3-Chloro-4-Fluoroaniline	0.95 kg.
		2	Diethyl Ethoxy Methylene Malonate	1.41 kg.
		3	Toluene	2.96 kg.
		4	Methanol	3.53 kg.
		5	Piperazine Anhydrous	0.665 kg.

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

Case No.	26 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	CATION PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008519AM24
RA File Number	52AX04000341 AM24
Licence No and Date	5211007357/12/02/2024
Norms Committee Decision:	
Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
Complete chemistry, Molecular weight and percentage yield on molar basis.	

Case No.	27 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	ATUL LIMITED
Meeting Number	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024

and Date	
HQ File Number	HQRNORM APPLY 00008531AM24
RA File Number	08AX04002041 AM24
Licence No and Date	0811010749/13/02/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical reaction indicating molecular weight of reactants and products indicating yield of the reaction with justification. 2. End use of the Export Item.	

Case No.	28 / NC/3/MEET/Nov/202425/10																		
Case Status	Case Approved																		
Party Name	MANKIND PHARMA LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024																		
HQ File Number	HQRNORM APPLY 00008554AM24																		
RA File Number	05AX04003657 AM24																		
Licence No and Date	0511023947/13/02/2024																		
Norms Committee Decision:																			
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/202324/20 dated 18/01/2024 against advance authorization No.0511018497 dated 25/04/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																			
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Ofloxacin Otic Solution, 5ml (Having net content of 29.35 kg of Bulk Drug (filling volume 5.4 ml in each number))</td><td>1 Number</td><td>1</td><td>OFLOXACIN USP</td><td>15.30 mg.</td></tr><tr><td>Ofloxacin Otic Solution, 10ml (Having net content of 24.46 kg of Bulk Drug (filling volume 10.65 ml in each Number)</td><td>1 Number</td><td>2</td><td>OFLOXACIN USP</td><td>30.60 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ofloxacin Otic Solution, 5ml (Having net content of 29.35 kg of Bulk Drug (filling volume 5.4 ml in each number))	1 Number	1	OFLOXACIN USP	15.30 mg.	Ofloxacin Otic Solution, 10ml (Having net content of 24.46 kg of Bulk Drug (filling volume 10.65 ml in each Number)	1 Number	2	OFLOXACIN USP	30.60 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Ofloxacin Otic Solution, 5ml (Having net content of 29.35 kg of Bulk Drug (filling volume 5.4 ml in each number))	1 Number	1	OFLOXACIN USP	15.30 mg.															
Ofloxacin Otic Solution, 10ml (Having net content of 24.46 kg of Bulk Drug (filling volume 10.65 ml in each Number)	1 Number	2	OFLOXACIN USP	30.60 mg.															

Ofloxacin Ophthalmic Solution, USP, 5ml (Having net content of 61.68 kg of Bulk Drug (filling volume 5.4 ml in each number))	1 Number	3	OFLOXACIN USP	15.30 mg.
Ofloxacin Ophthalmic Solution, USP, 10ml (Having net content of 7.16 kg of Bulk Drug (filling volume 10.65 ml in each number))	1 Number	4	OFLOXACIN USP	30.60 mg.

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

Case No.	29 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008564AM24
RA File Number	03AX04005181 AM24
Licence No and Date	0311031166/14/02/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CHLORAMPHENICOL (VANMYCETIN) EYE DROPS 10 ML (CLORAH EYE DROPS 10 ML AND OPTIPHEN OPHTHALMIC SOLUTIONS 5 mg/ml 10ML)(EACH VIAL CONTAINS CHLORAMPHENICOL MICRONIZED 0.050 GM NET	297000 Vials	1	CHLORAMPHENICOL MICRONIZED	15.145 kg.

WT OF BULK DRUG IS 14.850 KGS))

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

Case No.	30 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008566AM24
RA File Number	05AX04003666 AM24
Licence No and Date	0511023953/14/02/2024

Norms Committee Decision:

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/202324/8 dated 30/06/2023** against advance authorization **No.0911004779 dated 29/03/.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.
Nitroglycerin Sublingual Tablets USP, 0.3mg	1 Number	1	DILUTED NITROGLYCERIN USP (2% W/W)	15.70 mg.
Nitroglycerin Sublingual Tablets USP, 0.4mg	1 Number	2	DILUTED NITROGLYCERIN USP (2% W/W)	20.93 mg.
Nitroglycerin Sublingual Tablets USP, 0.6mg	1 Number	3	DILUTED NITROGLYCERIN USP (2% W/W)	31.40 mg.

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

Case No.	31 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	BASIL DRUGS AND PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008570AM24
RA File Number	03AX04005041 AM24
Licence No and Date	0311031186/14/02/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete chemistry, molecular weight and percentage yield on molar basis for each export item. 2. Past production/consumption data duly certified by CA.	

Case No.	32 / NC/3/MEET/Nov/202425/10										
Case Status	Case Approved										
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024										
HQ File Number	HQRNORM APPLY 00008616AM24										
RA File Number	03AX04005267 AM24										
Licence No and Date	0311031276/16/02/2024										
Norms Committee Decision:											
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Procyclidine 5mg Tablets</td><td>1 Number</td><td>1</td><td>Procyclidine Hydrochloride</td><td>5.10 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Procyclidine 5mg Tablets	1 Number	1	Procyclidine Hydrochloride	5.10 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Procyclidine 5mg Tablets	1 Number	1	Procyclidine Hydrochloride	5.10 mg.							

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

Case No.	33 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	VIDACARE MEDICA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008647AM24
RA File Number	03AX04005005 AM24
Licence No and Date	0311031320/19/02/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TETRACYCLLINE HCL CAPSULE BP 250 MG EACH CAPSULE CONTAINS:TETRACYCLLINE HCL BP 250MG 400000 X 10X10 C)	40000000 Numbers	1	TETRACYCLINE HCL BP/USP/EP	10200 kg.
DEVITHRO- 500 TABLETS ERYTHROMYCIN STEARATE TABLETS BP 500 MG EACH FILM COATED TABLET CONTAINS: ERYTHROMYCIN STEARATE BP (693.789 MG) EQ. TO ERYTHROMYCIN BP 500 MG 111006.24 X 10 X 10 T)	11100624 Numbers	2	ERYTHROMYCIN STEARATE BP/USP/EP	5661.31 kg.
DEVITHRO- 250 TABLETS ERYTHROMYCIN STEARATE TABLETS BP 250 MG EACH FILM COATED TABLET CONTAINS : ERYTHROMYCIN STEARATE BP (346.89 MG) EQ. TO	9798671 Numbers	3	ERYTHROMYCIN STEARATE BP/USP/EP	2498.66 kg.

ERYTHROMYCIN BP 250 MG 97986.71 X 10 X 10 T)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	34 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008661AM24
RA File Number	07AX04001821 AM24
Licence No and Date	0711010591/21/02/2024
Norms Committee Decision:	
Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical reaction indicating molecular weight of reactants and products, giving yield of the reaction with justification. 2. End use of the export item. 3. A copy of minutes of meeting, if the norms have been approved for the item, in the past.	

Case No.	35 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008671AM24
RA File Number	07AX04001818 AM24
Licence No and Date	0711010595/21/02/2024
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MAGNESIUM OROTATE	1 MT	1	OROTIC ACID (Monohydrate)	0.990 MT
CALCIUM OROTATE	1 MT	2	OROTIC ACID (Monohydrate)	0.948 MT
POTASSIUM OROTATE	1 MT	3	OROTIC ACID (Monohydrate)	0.944 MT
ZINC OROTATE	1 MT	4	OROTIC ACID (Monohydrate)	0.890 MT
FERROUS OROTATE	1 MT	5	OROTIC ACID (Monohydrate)	0.872 MT

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

Case No.	36 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008680AM24
RA File Number	08AX04002108 AM24
Licence No and Date	0811010830/21/02/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cupric Chloride Injection USP, 0.4 mg/mL (10 mL)	1 Number	1	Copper (II) chloride dihydrate GMP	11.77 mg.

Case No.	38 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008696AM24
RA File Number	03AX04005309 AM24
Licence No and Date	0311031390/22/02/2024
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202425/2 dated 30/04/2024 against advance authorization No.0311024276 dated 06/06/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Carbamazepine Extended-Release Tablets USP 100 mg. Each tablet contains (i) Carbamazepine 100 mg.(ii) Cellulose Acetate (CA-320S) -Eastman 35.04mg. (iii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 5.28 mg.	1 Number	1	Carbamazepine	102.00 mg.
		2	Cellulose Acetate (CA 320S) Eastman	29.20 mg.
		3	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.
Carbamazepine Extended-Release Tablets USP 200 mg. Each tablet contains (i) Carbamazepine 200 mg.(ii) Cellulose Acetate (CA-320S) -Eastman 35.04mg. (iii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 5.28 mg	1 Number	4	Carbamazepine	204.00 mg.
		5	Cellulose Acetate (CA 320S) Eastman	29.20 mg.
		6	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.
Carbamazepine Extended-Release Tablets USP 400 mg. Each tablet contains (i) Carbamazepine 400 mg.(ii) Cellulose Acetate (CA-320S) -Eastman 26.28mg. (iii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 3.96 mg	1 Number	7	Carbamazepine	408.00 mg.
		8	Cellulose Acetate (CA 320S) Eastman	29.20 mg.
		9	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.

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

Case No.	39 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	HIND PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008700AM24
RA File Number	56AX04000681 AM24
Licence No and Date	5611002746/22/02/2024

Norms Committee Decision:

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

Copy of DML for each export item showing approved composition.

Case No.	40 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	MEONE HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008751AM24
RA File Number	04AX04001035 AM24
Licence No and Date	0411006998/26/02/2024

Norms Committee Decision:

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

- i. **Copy of DML for the export product showing approved composition.**
- ii. **CoA of import item from foreign supplier.**
- iii. **Complete calculation sheet to arrive at applied norms.**

Case No.	41 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	EAST AFRICAN INDIA OVERSEAS
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008755AM24
RA File Number	05AX04003663 AM24
Licence No and Date	0511023926/26/02/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
VIREXIM 1GM INJECTION (CEFTRIAZONE INJECTION USP 1 GM)	1 Number	1	STERILE CEFTRIAZONE SODIUM IP	1.16 gm.
CEFTRIAZONE 1GM INJECTION (CEFTRIAZONE INJECTION USP FOR INJECTION 1GM)	1 Number	2	STERILE CEFTRIAZONE SODIUM IP	1.16 gm.

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

Case No.	42 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008761AM24
RA File Number	03AX04005401 AM24
Licence No and Date	0311031503/27/02/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	43 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	S KANT CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008762AM24
RA File Number	03AX04005393 AM24
Licence No and Date	0311031505/27/02/2024

Norms Committee Decision:

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/202324/21 dated 24/01/2024** against advance authorization **No.0811008267 dated 24/05/2023** , 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.
DEXAMETHASONE IP	1 kg.	1	16ALPHA-METHYL EPOXIDE (8DM)	0.811 kg.

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

Case No.	44 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008765AM24
RA File Number	03AX04005326 AM24
Licence No and Date	0311031507/27/02/2024

Norms Committee Decision:

Decision: The Committee considered the request of firm for fixation of ad-hoc norms and it appears that item of export under license is perfumery compounds and same comes under para 4.11(b) of FTP, 2023, and the said para states that “For export of perfumes, perfumery compounds and various feed ingredients containing vitamins, no authorisation shall be issued by Regional Authority under para 4.07 of HBP and applicants shall be required to apply under para 4.06 of HBP to the Norms Committee”.

1. The Committee decided that a clarification in this regard may be furnished by the firm as well by RA concerned.

Case No.	45 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved

Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008773AM24
RA File Number	08AX04002087 AM24
Licence No and Date	0811010888/27/02/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ISOFLURANE USP/BP/IP/CEP/EP/ChP 250ML (LIQUID FOR INHALATION) EACH BOTTLE CONTAINS ISOFLURANE USP 250ML EQUIVALENT TO 372.96GMS)	10000 Numbers	1	ISOFLURANE	3729.6 kg.
ISOFLURANE USP/BP/IP/CEP/EP/ChP 100ML (LIQUID FOR INHALATION) EACH BOTTLE CONTAINS ISOFLURANE USP 100ML EQUIVALENT TO 149.48GMS)	12000 Numbers	2	ISOFLURANE	1793.76 kg.
ISOFLURANE USP/BP/IP/CEP/EP/ChP 30ML (LIQUID FOR INHALATION) EACH BOTTLE CONTAINS ISOFLURANE USP 30ML EQUIVALENT TO 45.88GMS)	2000 Number	3	ISOFLURANE	91.76 kg.

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

Case No.	46 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024										
HQ File Number	HQRNORM APPLY 00008780AM24										
RA File Number	03AX04005442 AM24										
Licence No and Date	0311031542/27/02/2024										
Norms Committee Decision: 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 authorization No.0311033003 dated 15/04/2024, 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:- <table border="1" data-bbox="197 750 1428 948"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Vibegron (Gemtesa)Tablets 75 mg</td> <td>1 Number</td> <td>1</td> <td>Vibegron</td> <td>76.50 mg/Tablet</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.	Vibegron (Gemtesa)Tablets 75 mg	1 Number	1	Vibegron	76.50 mg/Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Vibegron (Gemtesa)Tablets 75 mg	1 Number	1	Vibegron	76.50 mg/Tablet							

Case No.	47 / NC/3/MEET/Nov/202425/10				
Case Status	Case Approved				
Party Name	ENCUBE ETHICALS PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024				
HQ File Number	HQRNORM APPLY 00008783AM24				
RA File Number	03AX04005399 AM24				
Licence No and Date	0311031475/28/02/2024				
Norms Committee Decision: Decision: The Committee considered the request of firm in details and also discussed report of factory visit. The committee found that in the above mention case export product is in form of Gel not a cream/Ointments and accordingly decided to fix the ad-hoc norms as under :- <table border="1" data-bbox="173 1866 1428 2027"> <thead> <tr> <th>Sl. No</th> <th>Export Product</th> <th>Quantity</th> </tr> </thead> <tbody> </tbody> </table>			Sl. No	Export Product	Quantity
Sl. No	Export Product	Quantity			

(i)	Medical Cream and Ointment(Azelaic Acid 15% Gel 50 Gm Tot WT 7,500Kgs. (Net Cont :Azelaic 1,125Kgs, Benzoic 7.50Kg, Edetate Dis 7.50 Kgs, Carbopol 75Kgs, Polysorbate 112.5 Kgs, Propylene 900 Kgs))	1 Number
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Sl. No.	Import Items	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 and General Notes.

Note: 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.	48 / NC/3/MEET/Nov/202425/10			
Case Status	Case Approved			
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024			
HQ File Number	HQRNORM APPLY 00008792AM24			
RA File Number	08AX04002148 AM24			
Licence No and Date	0811010899/28/02/2024			

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Phenylephrine Hydrochloride Injection USP, 10 mg/mL (5 mL)	1 Vial	1	Phenylephrine HCl USP/Ph.Eur	55 mg/Vial
Phenylephrine Hydrochloride Injection USP, 10 mg/mL (10 mL)	1 Vial	2	Phenylephrine HCl USP/Ph.Eur	110 mg/Vial

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

Case No.	49 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008801AM24
RA File Number	03AX04005270 AM24
Licence No and Date	0311031579/28/02/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Buspirone HCl Tablet 5mg	1 Number	1	Buspirone HCl USP	5.10 mg.
		2	Lactose Monohydrate NF	80.0 mg.
		3	Croscarmellose Sodium USP-NF (Ac-Di-Sol)	0.50 mg.
Buspirone HCl Tablet 7.5mg	1 Number	4	Buspirone HCl USP	7.65 mg.
		5	Lactose Monohydrate NF	120.0 mg.

		6	Croscarmellose Sodium USP-NF (Ac-Di-Sol)	0.75 mg.
Buspirone HCl Tablet 10 mg	1 Number	7	Buspirone HCl USP	10.2 mg
		8	Lactose Monohydrate NF	160.0 mg
		9	Croscarmellose Sodium USP-NF (Ac-Di-Sol)	1.00 mg.
Buspirone HCl Tablet 15 mg	1 Number	10	Buspirone HCl USP	15.30 mg.
		11	Lactose Monohydrate NF	240.0 mg
		12	Croscarmellose Sodium USP-NF (Ac-Di-Sol)	1.50 mg.
Buspirone HCl Tablet 30 mg	1 Number	13	Buspirone HCl USP	30.6 mg.
		14	Lactose Monohydrate NF	480.0 mg.
		15	Croscarmellose Sodium USP-NF (Ac-Di-Sol)	3.00 mg.
Acetazolamide Tab USP 125mg	1 Number	16	Acetazolamide USP	127.50 mg.
		17	Lactose Monohydrate NF	51.10 mg.
		18	Sodium Starch Glycolate NF	7.50 mg.
Acetazolamide Tab USP 250 mg	1 Number	19	Acetazolamide USP	255.0 mg.
		20	Lactose Monohydrate NF	102.30 mg.
		21	Sodium Starch Glycolate NF	15.00 mg.
Metoprolol Tartrate Tablets 25 mg	1 Number	22	Metoprolol Tartrate USP	25.50 mg.
		23	Lactose Monohydrate NF	26.0 mg.

		24	Sodium Starch Glycolate NF	10.00 mg.
Metoprolol Tartrate Tablets 37.50mg	1 Number	25	Metoprolol Tartrate USP	38.25 mg.
		26	Lactose Monohydrate NF	39.00 mg.
		27	Sodium Starch Glycolate NF	15.00 mg.
Metoprolol Tartrate Tablets 50mg	1 Number	28	Metoprolol Tartrate USP	51.0 mg.
		29	Lactose Monohydrate NF	78.0 mg.
		30	Sodium Starch Glycolate NF	20.0 mg.
Metoprolol Tartrate Tablets 75mg	1 Number	31	Metoprolol Tartrate USP	76.5 mg.
		32	Lactose Monohydrate NF	78.0 mg.
		33	Sodium Starch Glycolate NF	30.0 mg.
Metoprolol Tartrate Tablets 100mg	1 Number	34	Metoprolol Tartrate USP	102.0 mg.
		35	Lactose Monohydrate NF	104.0 mg.
		36	Sodium Starch Glycolate NF	40.0 mg.
Oxybutynin Chloride ER Tab USP 5mg	1 Number	37	Oxybutynin Chl USP	5.10 mg.
		38	Lactose Monohydrate NF	15.33 mg.
Oxybutynin Cl ER Tab USP 10mg	1 Number	39	Oxybutynin Chl USP	10.20 mg.
		40	Lactose Monohydrate NF	30.65 mg.
Oxybutynin Chloride ER Tab USP 15mg	1 Number	41	Oxybutynin Chl USP	15.30 mg.
		42	Lactose Monohydrate NF	25.75 mg.

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

Case No.	50 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	MAXMED LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008802AM24
RA File Number	05AX04003602 AM24
Licence No and Date	0511024076/28/02/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Nov/202425/10 dated 22/11/2024** against advance authorization **No.0511024076 dated 28/02/2024**, 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.
Amoxycillin oral suspension (Amoxycillin Syrup) 250 mg/5 ml, 60 ml Bottle (Each 5 ml contains Amoxycillin Trihydrate equivalent to 250 mg of Amoxycillin))	1500000 Numbers	1	Amoxycillin Trihydrate	5423.0 kg.

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

Case No.	51 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024

HQ File Number	HQRNORM APPLY 00008814AM24										
RA File Number	05AX04003827 AM24										
Licence No and Date	0511024211/29/02/2024										
Norms Committee Decision: Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Nov/202425/10 dated 22/11/2024 against advance authorization No.0511024211 dated 29/02/2024, 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:- <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>VANCOMYCIN HYDROCHLORIDE (STERILE)</td><td>1 kg</td><td>1</td><td>Vancomycin HCL (Non Sterile)</td><td>1.01 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.	VANCOMYCIN HYDROCHLORIDE (STERILE)	1 kg	1	Vancomycin HCL (Non Sterile)	1.01 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
VANCOMYCIN HYDROCHLORIDE (STERILE)	1 kg	1	Vancomycin HCL (Non Sterile)	1.01 kg.							

Case No.	52 / NC/3/MEET/Nov/202425/10					
Case Status	Case Approved					
Party Name	ALEMBIC PHARMACEUTICALS LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024					
HQ File Number	HQRNORM APPLY 00008824AM24					
RA File Number	34AX04000861 AM24					
Licence No and Date	3411004655/29/02/2024					
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.		

Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution, USP 2% & 0.5% - 10 ML	1 Number	1	Timolol Maleate USP	69.67 mg.
Brimonidine Tartrate and Timolol Maleate Ophthalmic solution 0.2% & 0.5% - 5 ML	1 Number	2	Timolol Maleate USP	34.68 mg.
Brimonidine Tartrate and Timolol Maleate Ophthalmic solution 0.2% & 0.5% -10 ML	1 Number	3	Timolol Maleate USP	69.36 mg.
Brimonidine Tartrate and Timolol Maleate Ophthalmic solution 0.2% & 0.5% - 15 ML	1 Number	4	Timolol Maleate USP	104.04 mg.
Timolol Maleate Ophthalmic Gel Forming Solution, 0.5% - 5 ML	1 Number	5	Timolol Maleate USP	34.68 mg.
Timolol Maleate Ophthalmic Gel Forming Solution, 0.25% - 5 ML	1 Number	6	Timolol Maleate USP	17.34 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	53 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008826AM24
RA File Number	03AX04005194 AM24
Licence No and Date	0311031599/29/02/2024
Norms Committee Decision:	
Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	

1. **Copy of Master Batch Formula.**
2. **Copy of Drug Manufacturing Licence (DML).**

Case No.	54 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00008831AM24
RA File Number	08AX04002140 AM24
Licence No and Date	0811010931/29/02/2024

Norms Committee Decision:

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 authorization **No.0811011227 dated 04/04/2024**, 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.
CANDESARTAN CILEXETIL 2 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 2 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 8.719 KG IN EXPORT ITEM)	1 Number	1	CANDESARTAN CILEXETIL PH.EUR	2.04 mg.
CANDESARTAN CILEXETIL 4 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 4 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 21.797 KG IN EXPORT ITEM)	1 Number	2	CANDESARTAN CILEXETIL PH.EUR	4.08 mg.
CANDESARTAN CILEXETIL 8 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 8 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 196.468 KG IN EXPORT ITEM)	1 Number	3	CANDESARTAN CILEXETIL PH.EUR	8.16 mg.

CANDESARTAN CILEXETIL 16 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 16 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 435.949 KG IN EXPORT ITEM)	1 Number	4	CANDESARTAN CILEXETIL PH.EUR	16.32 mg.
CANDESARTAN CILEXETIL 32 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 32 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 674.268 KG IN EXPORT ITEM)	1 Number	5	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 8 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 8 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 8.138 KG IN EXPORT ITEM)	1 Number	6	CANDESARTAN CILEXETIL PH.EUR	8.16 mg
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 16 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 16 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 34.876 KG IN EXPORT ITEM)	1 Number	7	CANDESARTAN CILEXETIL PH.EUR	16.32 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 20.926 KG IN EXPORT ITEM)	1 Number	8	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32 MG +25 MG(EACH UNCOATED TABLET	1 Number	9	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.

CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH EUR. 25 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 41.851 KG IN EXPORT ITEM)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	55 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000504AM25
RA File Number	03AX04000497 AM25
Licence No and Date	0311033495/01/05/2024

Norms Committee Decision:

Decision: The Committee considered the request of firm in details and also discussed report of factory visit. The committee found that in the above mention case export product is in form of Gel not a cream/Ointments and accordingly decided to fix the ad-hoc norms as under :-

Sl. No	Export Product	Quantity
(i)	Medical Cream & Onitment(Mesalamine Rectal Suspension, USP Enema 4.0 g/ 60 ml (Tot Wt: 73944 Kgs(Net Cont: Mesalamine 5028.19 Kgs, POTASSIUM METABISULFITE NF 347.54 , POTASSIUM ACETATE 303.17 kgs LDPE Bottle 1200000 Nos, Enema Applicator 1200000 Nos.))	1 Number

Sl. No.	Import Items	Quantity allowed.
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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 and General Notes.

Note: 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.	56 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000508AM25
RA File Number	03AX04000230 AM25
Licence No and Date	0311033504/01/05/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Nov/202425/10 dated 22/11/2024** against advance authorization **No.0311033504 dated 01/05/2024**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NAPROLAT-CARBOPLATIN BP 10 MG/ML INJ. (1x15ML) 150 MG.	1 Vial	1	Carboplatin IP/ BP/ USP	157.5 mg/Vial
NAPROLAT-CARBOPLATIN BP 10 MG/ML INJ. (1x45ML) 450 MG.	1 Vial	2	Carboplatin IP/ BP/ USP	472.50 mg/Vial

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

Case No.	57 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000517AM25
RA File Number	08AX04000152 AM25
Licence No and Date	0811011425/02/05/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. CoA of import item from Foreign Supplier. 2. Copy of Drug Manufacturing License (DML). 3. Vial size of export item in ML.	

Case No.	58 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	SANPRAS HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000523AM25
RA File Number	31AX04000022 AM25
Licence No and Date	3111003394/02/05/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Composition of export item and wastage claimed in each step of manufacturing process. 2. CoA of export item. 3. CoA of import item from Foreign Supplier.	

4. Copy of Batch-Log Sheet for previous three consecutive batches.

Case No.	59 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000534AM25
RA File Number	03AX04000479 AM25
Licence No and Date	0311033556/03/05/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Nov/202425/10 dated 22/11/2024** against advance authorization **No.0311033556 dated 03/05/2024**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Nifedipine Extended-Release Tablets 30mg. Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 56.80 mg(ii) Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)- 33.12 mg (iii) SENTRY POLYOX WSR N80 FP NF - 118.40 mg.	1 Number	1	SENTRY POLYOX WSR COAGULANT NF	56.8 mg.
		2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	33.12 mg.
		3	SENTRY POLYOX WSR N80 FP NF	118.40 mg.
Nifedipine Extended-Release Tablets 60mg. Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 113.60 mg(ii) Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)- 42.32 mg (iii) SENTRY POLYOX WSR N80 FP NF - 236.80 mg.	1 Number	4	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	113.60 mg.
		5	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	42.32 mg.

		6	SENTRY POLYOX WSR N80 FP NF	236.80 mg.
Nifedipine Extended-Release Tablets 90mg. Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 162.90 mg(ii) Eastman (TM Cellulose Acetate (CA 398- 10NF/EP)- 64.80 mg (iii) SENTRY POLYOX WSR N80 FP NF - 369.90 mg.	1 Number	7	SENTRY POLYOX WSR COAGULANT NF	162.9 mg.
		8	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	64.80 mg.
		9	SENTRY POLYOX WSR N80 FP NF	369.90 mg.

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

Case No.	60 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000535AM25
RA File Number	03AX04000486 AM25
Licence No and Date	0311033558/03/05/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Drug Manufacturing License. 2. Copy of Master-Batch Formula.	

Case No.	61 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024										
HQ File Number	HQRNORM APPLY 00000560AM25										
RA File Number	03AX04000294 AM25										
Licence No and Date	0311033608/06/05/2024										
Norms Committee Decision:											
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<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>ROSUVASTATIN TABLET BP / USP 20 MG. (Each Tablet contains Rosuvastatin Calcium 20.800 mg) Eq. to Rosuvastatin 20 mg.</td><td>47135000 Numbers</td><td>1</td><td>Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate</td><td>1299.4 kg.</td></tr> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ROSUVASTATIN TABLET BP / USP 20 MG. (Each Tablet contains Rosuvastatin Calcium 20.800 mg) Eq. to Rosuvastatin 20 mg.	47135000 Numbers	1	Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate	1299.4 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
ROSUVASTATIN TABLET BP / USP 20 MG. (Each Tablet contains Rosuvastatin Calcium 20.800 mg) Eq. to Rosuvastatin 20 mg.	47135000 Numbers	1	Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate	1299.4 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	62 / NC/3/MEET/Nov/202425/10					
Case Status	Case Approved					
Party Name	CDYMAX (INDIA) PHARMA PRIVATE LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024					
HQ File Number	HQRNORM APPLY 00000561AM25					
RA File Number	07AX04000123 AM25					
Licence No and Date	0711011233/06/05/2024					
Norms Committee Decision:						
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-						
<table border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.		

Capecitabine	1 kg.	1	2, 3-Di-O-ACETYL-5-DEOXY-5-FLUOROCYTIDINE	1.00 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	63 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	HEMA DYECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000568AM25
RA File Number	03AX04000390 AM25
Licence No and Date	0311033616/06/05/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical reaction indicating molecular weight of reactants and products with stage wise yield. 2. Calculation of requirement of raw materials, (both imported and indigenous) with justification of yield of the reaction. 3. To indicate indigenous items in Appendix- 4E with technical details of the annexure.	

Case No.	64 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000569AM25
RA File Number	03AX04000513 AM25
Licence No and Date	0311033617/06/05/2024
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
AZELAIC ACID GEL 15 percent (Pack Size 50 Grams) (Net Wt. of Azelaic Acid is 1425.00 Kgs.)	190000 Numbers	1	Azelaic Acid	1453.50 kg.

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

Case No.	65 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	DEEPAK CHEM TECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000594AM25
RA File Number	34AX04000083 AM25
Licence No and Date	3411004899/08/05/2024

Norms Committee Decision:

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

- 1. Chemical reaction indicating molecular weight of reactants and products with stage wise yield.**
- 2. Calculation of requirement of raw materials, (both imported and indigenous) with justification of yield of the reaction.**
- 3. To indicate indigenous items in Appendix-4E with technical details of the annexure.**
- 4. Stoichiometric material balance on a molar basis.**
- 5. In the process flow chart do not use abbreviations, instead to give full names**

Case No.	66 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	DEEPAK CHEM TECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000595AM25
RA File Number	34AX04000021 AM25
Licence No and Date	3411004900/08/05/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical reaction indicating molecular weight of reactants and products with stage wise yield. 2. Calculation of requirement of raw materials, (both imported and indigenous) with justification of yield of the reaction. 3. To indicate indigenous items in Appendix-4E with technical details of the annexure. 4. Stoichiometric material balance on a molar basis. 5. In the process flow chart do not use abbreviations, instead to give full names.	

Case No.	67 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000598AM25
RA File Number	03AX04000571 AM25
Licence No and Date	0311033662/08/05/2024
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cetylpyridinium Chloride And Benzydamine Hydrochloride Antiseptic Lozenges Sugar Free.(Each lozenge contains (i) Cetylpyridinium Chloride- 1 mg (ii) Benzydamine Hydrochloride - 3 mg (iii) Isomalt ST-M - 2471.285 mg.	1 Number	1	Cetylpyridinium Chloride	1.00 mg/Lozen
		2	Benzydamine Hydrochloride	3.06 mg/Lozen
		3	Isomalt ST-M	2471.285 mg/Lozen

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

Case No.	68 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000608AM25
RA File Number	03AX04000430 AM25
Licence No and Date	0311033683/08/05/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	69 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000616AM25
RA File Number	08AX04000190 AM25
Licence No and Date	0811011469/09/05/2024
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Benzylpenicillin sodium 3mg (5mui) injection	1 Number	1	Benzylpenicillin sodium	3.042 mg.

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

Case No.	70 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000626AM25
RA File Number	08AX04000176 AM25
Licence No and Date	0811011484/09/05/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ropivacaine Hydrochloride Inj 200 mg/100 mL	1 Vial	1	Ropivacaine	210 mg/Vial
Ropivacaine Hydrochloride Inj 400 mg/200 mL	1 Vial	2	Ropivacaine	420 mg/Vial
Ropivacaine Hydrochloride Inj 500 mg/100 mL	1 Vial	3	Ropivacaine	525 mg/Vial

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

Case No.	71 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000642AM25
RA File Number	03AX04000610 AM25
Licence No and Date	0311033714/09/05/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Apr/202425/2 dated 30/04/2024** against advance authorization **No.0311024666 dated 19/06/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NAPROLAT-CARBOPLATIN BP 10 MG/ML INJ. (1x45ML) 450 MG.	Number Vial	1	Carboplatin IP/ BP/ USP/EP	472.50 mg/45 ml. Injection

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

Case No.	72 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	JUBILANT GENERICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000653AM25

RA File Number	05AX04000387 AM25			
Licence No and Date	0511025423/10/05/2024			
Norms Committee Decision:				
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/202324/14 dated 27/09/2023 against advance authorization No.0511020697 dated 29/08/2023, 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.
Losartan Potassium 25 mg	1 Tablet	1	Losartan Potassium Ph.Eur (UK)	25.50 mg.
Losartan Potassium 50 mg	1 Tablet	2	Losartan Potassium Ph.Eur (UK)	51.00 mg.
Losartan Potassium 100 mg	1 Tablet	3	Losartan Potassium Ph.Eur (UK)	102.00 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	73 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	K.P.MANISH GLOBAL INGREDIENTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000654AM25
RA File Number	04AX04000110 AM25
Licence No and Date	0411007398/10/05/2024
Norms Committee Decision:	
Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	

1. **Molecular weight not given in the reaction.**
2. **Whether export item is Pseudomonic Acid A only and confirm to which Pharmacopeia?**
3. **Copy of CoA of Export item.**
4. **CoA of import item from Foreign Supplier.**
5. **Percentage yield for purification.**

Case No.	74 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	NECTAR LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000693AM25
RA File Number	30AX04000069 AM25
Licence No and Date	3011005168/13/05/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	75 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	PRIGIV SPECIALTIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000698AM25
RA File Number	03AX04000618 AM25
Licence No and Date	0311033818/14/05/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	76 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024																							
HQ File Number	HQRNORM APPLY 00000700AM25																							
RA File Number	08AX04000215 AM25																							
Licence No and Date	0811011547/14/05/2024																							
Norms Committee Decision:																								
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																								
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Propofol Injectable Emulsion, USP 200 mg per 20 mL (10 mg per mL)</td><td>1 Vial</td><td>1</td><td>Propofol</td><td>210 mg/Vial</td></tr><tr><td>Propofol Injectable Emulsion, USP 500 mg per 50 mL (10 mg per mL)</td><td>1 Vial</td><td>2</td><td>Propofol</td><td>525 mg/Vial</td></tr><tr><td>Propofol Injectable Emulsion, USP 1,000 mg per 100 mL (10 mg per mL)</td><td>1 Vial</td><td>3</td><td>Propofol</td><td>1050 mg/Vial</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Propofol Injectable Emulsion, USP 200 mg per 20 mL (10 mg per mL)	1 Vial	1	Propofol	210 mg/Vial	Propofol Injectable Emulsion, USP 500 mg per 50 mL (10 mg per mL)	1 Vial	2	Propofol	525 mg/Vial	Propofol Injectable Emulsion, USP 1,000 mg per 100 mL (10 mg per mL)	1 Vial	3	Propofol	1050 mg/Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																				
Propofol Injectable Emulsion, USP 200 mg per 20 mL (10 mg per mL)	1 Vial	1	Propofol	210 mg/Vial																				
Propofol Injectable Emulsion, USP 500 mg per 50 mL (10 mg per mL)	1 Vial	2	Propofol	525 mg/Vial																				
Propofol Injectable Emulsion, USP 1,000 mg per 100 mL (10 mg per mL)	1 Vial	3	Propofol	1050 mg/Vial																				
RA concerned may take further necessary action as per above decision of NC.																								

Case No.	77 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000703AM25
RA File Number	05AX04000448 AM25
Licence No and Date	0511025482/14/05/2024
Norms Committee Decision:	
Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	

Justification for low yield of 69.2%

Case No.	78 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000706AM25
RA File Number	05AX04000432 AM25
Licence No and Date	0511025488/14/05/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Moxifloxacin HCL and Dexamethasone Sodium Phosphate Eye Drops 0.5%w/v, 0.1% w/v, 5ml ((Each ml contain Moxifloxacin Base 5mg. equi. to Moxifloxacin HCL 5.45mg. & Dexamethasone Phosphate 1mg equi. to Dexamethasone Sodium Phosphate 1.1mg (Equi.to 2452.500gm Moxifloxacin HCL and 495.000gm Dexamethasone Sodium Phosphate Bulk Drug))	90000 Numbers	1	Moxifloxacin Hydrochloride	2575.125 gram
		2	Dexamethasone Sodium Phosphate	519.75 gram

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

Case No.	79 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred

Party Name	S KANT HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000712AM25
RA File Number	03AX04000705 AM25
Licence No and Date	0311033849/14/05/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	80 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	JALAQUA INTERNATIONAL LLP
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000722AM25
RA File Number	52AX04000032 AM25
Licence No and Date	5211008159/15/05/2024
Norms Committee Decision:	
Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical reaction indicating molecular weight of reactants and products with yield. 2. Calculation of requirement of raw materials, (both imported and indigenous) with justification of yield of the reaction. 3. To indicate indigenous items in Appendix-4E with technical details of the annexure. 4. Stoichiometric material balance on a molar basis and commercial value of byproduct, if any.	

Case No.	81 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024

and Date	
HQ File Number	HQRNORM APPLY 00000729AM25
RA File Number	03AX04000711 AM25
Licence No and Date	0311033871/15/05/2024

Norms Committee Decision:

Decision: The Committee considered the request of firm in details and also discussed report of factory visit. The committee found that in the above mention case export product is in form of Gel not a cream/Ointments and accordingly decided to fix the ad-hoc norms as under :-

Sl. No	Export Product	Quantity
(i)	Medical Creams & Ointments(TRIAMCINOLONE ACETO OINT USP, 0.1% 454G Tot Wt. 40860 Kgs (Net Cont: Triamcinolone 40.86Kgs, Plastic Jars 90000 Nos, Plastic Caps 90000 Nos))	1 Number

Sl. No.	Import Items	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 and General Notes.

Note: 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.	82 / NC/3/MEET/Nov/202425/10
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Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000731AM25
RA File Number	03AX04000559 AM25
Licence No and Date	0311033874/15/05/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	83 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000733AM25
RA File Number	03AX04000685 AM25
Licence No and Date	0311033879/15/05/2024
Norms Committee Decision:	
Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete chemistry is not given to arrive at API. 2. Percentage yield on molar basis for each step. 3. Imort item No.2 should be specified as per the CoA of import item from Foreign Supplier. 4. Molecular weight of step 2 output is not matching with step 3 input.	

Case No.	84 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	S KANT HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000736AM25
RA File Number	03AX04000697 AM25
Licence No and Date	0311033882/15/05/2024

Norms Committee Decision:

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

Case No.	85 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000737AM25
RA File Number	34AX04000120 AM25
Licence No and Date	3411004931/15/05/2024

Norms Committee Decision:

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

Commercial value of low Boiler /High Boiler and residue alongwith invoices.

Case No.	86 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000745AM25
RA File Number	03AX04000666 AM25
Licence No and Date	0311033901/16/05/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Nov/202425/10 dated 22/11/2024** against advance authorization **No.0311033901 dated 16/05/2024**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Mometasone Furoate & Azelastine Hydrochloride Nasal Spray (150MD) / (DIRNELID AZ / MOMATE AZ) 150 MDI((Each Spray Deliver Mometasone Furoate 50mcg and Azelastine Hydrochloride 140 mcg) (Net Wt. of Import Sr. No. 1 is 11250 Grams and Import Sr. No.2 is 31500 Grams))	1500000 Numbers	1	Mometasone Furoate BP (Micronized)	11475 gram
		2	Azelastine Hydrochloride BP	32130 gram
Mometasone Furoate & Azelastine Hydrochloride Nasal Spray (75MD) / (DIRNELID AZ / MOMATE AZ) 75 MDI((Each Spray Deliver Mometasone Furoate 50mcg and Azelastine Hydrochloride 140 mcg) (Net Wt. of Import Sr. No. 1 is 4500 Grams and Import Sr. No.2 is 12600 Grams))	1200000 Numbers	3	Mometasone Furoate BP (Micronized)	4590 gram
		4	Azelastine Hydrochloride BP	12852 gram

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

Case No.	87 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000747AM25
RA File Number	07AX04000241 AM25
Licence No and Date	0711011310/16/05/2024
Norms Committee Decision:	
Decision: The committee considered the request of the firm for fixation of ad-hoc norms and it has been observed that the export item is Opipramol Dihydrochloride whereas the entire chemistry and norms working is given for Opipramol Hydrochloride, therefore, the committee decided that no norms can be proposed under the present details, given by the firm. Accordingly, the committee decided to seek a	

detailed reply from the firm on the matter.

Case No.	88 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000751AM25
RA File Number	03AX04000709 AM25
Licence No and Date	0311033876/16/05/2024

Norms Committee Decision:

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/202425/4 dated 06/06/2024** against advance authorization **No.0311024069 dated 31/05/2023**, 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.
Nifedipine Extended-Release Tablets 30mg. Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 56.80 mg (ii) Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)- 33.12 mg (iii) SENTRY POLYOX WSR N80 FP NF - 118.40 mg. Net content (i) 770 Kgs (ii) 448.99 Kgs (iii) 1605.07 Kgs.	1 Number	1	SENTRY POLYOX WSR COAGULANT NF	56.8 mg.
		2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	33.12 mg
		3	SENTRY POLYOX WSR N80 FP NF	118.40 mg.
Nifedipine Extended-Release Tablets 60mg. Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 113.60 mg (ii) Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)- 42.32 mg (iii) SENTRY POLYOX WSR N80 FP NF - 236.80 mg. Net content (i) 400 Kgs (ii) 149.01 Kgs (iii) 833.80 Kgs	1 Number	4	SENTRY POLYOX WSR COAGULANT NF	113.60 mg.
		5	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	42.32 mg.
		6	SENTRY POLYOX WSR N80 FP NF	236.80 mg.
Nifedipine Extended-Release Tablets 90mg.	1 Number	7	SENTRY POLYOX WSR COAGULANT NF	162.9 mg.

Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 162.90 mg (ii) Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)- 64.80 mg (iii) SENTRY POLYOX WSR N80 FP NF - 369.90 mg. Net content (i) 370.01 Kgs (ii) 147.19 Kgs (iii) 840.19 Kgs	8	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	64.80 mg.
	9	SENTRY POLYOX WSR N80 FP NF	369.90 mg.

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

Case No.	89 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000752AM25
RA File Number	03AX04000708 AM25
Licence No and Date	0311033875/16/05/2024

Norms Committee Decision:

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/202425/4 dated 06/06/2024** against advance authorization **No.0311024069 dated 31/05/2023**, 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.
Nifedipine Extended-Release Tablets 30mg. Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 56.80 mg(ii) Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)- 33.12 mg (iii) SENTRY POLYOX WSR N80 FP NF - 118.40 mg. Net content (i) 770 Kgs (ii) 448.99 Kgs (iii) 1605.07 Kgs.	1 Number	1	SENTRY POLYOX WSR COAGULANT NF	56.8 mg.
		2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	33.12 mg
		3	SENTRY POLYOX WSR N80 FP NF	118.40 mg.

Nifedipine Extended-Release Tablets 60mg. Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 113.60 mg(ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 42.32 mg (iii) SENTRY POLYOX WSR N80 FP NF - 236.80 mg. Net content (i) 400 Kgs (ii) 149.01 Kgs (iii) 833.80 Kgs	1 Number	4	SENTRY POLYOX WSR COAGULANT NF	113.60 mg.
		5	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	42.32 mg.
		6	SENTRY POLYOX WSR N80 FP NF	236.80 mg.
Nifedipine Extended-Release Tablets 90mg. Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 162.90 mg(ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 64.80 mg (iii) SENTRY POLYOX WSR N80 FP NF - 369.90 mg. Net content (i) 370.01 Kgs (ii) 147.19 Kgs (iii) 840.19 Kgs	1 Number	7	SENTRY POLYOX WSR COAGULANT NF	162.9 mg.
		8	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	64.80 mg.
		9	SENTRY POLYOX WSR N80 FP NF	369.90 mg.

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

Case No.	90 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	PRIGIV SPECIALTIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000772AM25
RA File Number	03AX04000620 AM25
Licence No and Date	0311033931/16/05/2024
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Luzernyl Butyrate	1 kg.	1	Cis-3-Hexenol	0.653 kg.
		2	Butyric acid	0.575 kg.

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

Case No.	91 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	COVALENT LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000773AM25
RA File Number	09AX04000101 AM25
Licence No and Date	0911007242/17/05/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
7-AMINO-3-VINYL-3-CEPHEM-4-CARBOXYLIC ACID (7-AVCA)(API)	1 kg.	1	7-Phenylacetamideo-3-Chloromethyl Cephalosporonic Acid Para Methoxybenzyl Ester (GCLE)	2.672 kg.
		2	Acetone	8.85 kg.
		3	Methylene Chloride	5.70 kg.
		4	Methanol	5.70 kg.

		5	Activated Carbon	0.100 kg.
		6	Triphenyl Phosphine	1.26 kg.

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

Case No.	92 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	VINS BIOPRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000776AM25
RA File Number	09AX04000030 AM25
Licence No and Date	0911007243/17/05/2024
Norms Committee Decision:	
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.	93 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000784AM25
RA File Number	05AX04000474 AM25
Licence No and Date	0511025589/17/05/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	94 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	MOREPEN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000787AM25
RA File Number	05AX04000479 AM25
Licence No and Date	0511025590/17/05/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete chemical description of export item alongwith copy of Shipping Bill in support of it. 2. CoA of Export Item.	

Case No.	95 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	PRIGIV SPECIALTIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000797AM25
RA File Number	03AX04000605 AM25
Licence No and Date	0311033967/17/05/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Manufactur process endorsed is for other product i.e. Luzernyl Butyrate.	

Case No.	96 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000852AM25
RA File Number	08AX04000258 AM25
Licence No and Date	0811011655/22/05/2024

Norms Committee Decision:

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 authorization **No.0811011227 dated 04/04/2024**, 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.
CANDESARTAN CILEXETIL 2 MG TABLETS(EACH UNCOATED TABLET CONTAINS: CANDESARTAN CILEXETIL PH. EUR 2 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 17.800 KG IN EXPORT ITEM)	1 Number	1	CANDESARTAN CILEXETIL PH.EUR	2.04 mg.
CANDESARTAN CILEXETIL 4 MG TABLETS(EACH UNCOATED TABLET CONTAINS: CANDESARTAN CILEXETIL PH. EUR 4 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 23.600 KG IN EXPORT ITEM)	1 Number	2	CANDESARTAN CILEXETIL PH.EUR	4.08 mg.
CANDESARTAN CILEXETIL 8 MG TABLETS(EACH UNCOATED TABLET CONTAINS: CANDESARTAN CILEXETIL PH. EUR 8 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 204.00 KG IN EXPORT ITEM)	1 Number	3	CANDESARTAN CILEXETIL PH.EUR	8.16 mg.
CANDESARTAN CILEXETIL 16 MG TABLETS(EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 16 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 408 KG IN EXPORT ITEM)	1 Number	4	CANDESARTAN CILEXETIL PH.EUR	16.32 mg.
CANDESARTAN CILEXETIL 32 MG TABLETS(EACH UNCOATED TABLET	1 Number	5	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.

CONTAINS : CANDESARTAN CILEXETIL PH. EUR 32 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 608.00 KG IN EXPORT ITEM)				
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZID E TABLETS 8 MG +12.5 MG (EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 8 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 10.400 KG IN EXPORT ITEM)	1 Number	6	CANDESARTAN CILEXETIL PH.EUR	8.16 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZID E TABLETS 16 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 16 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 22.400 KG IN EXPORT ITEM)	1 Number	7	CANDESARTAN CILEXETIL PH.EUR	16.32 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZID E TABLETS 32 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 27.200 KG IN EXPORT ITEM)	1 Number	8	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZID E TABLETS 32 MG +25 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH EUR. 25 MG NET CONTENT OF	1 Number	9	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.

CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 27.200 KG IN EXPORT ITEM)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	97 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000853AM25
RA File Number	08AX04000275 AM25
Licence No and Date	0811011659/22/05/2024

Norms Committee Decision:

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 authorization **No.0811011114 dated 27/03/2024**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tranexamic Acid Injection 100mg/mL (10mL)	1 Number	1	Tranexamic acid (Injectable grade, US FDA approved)	1.05 gm/100 ml. Vial

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

Case No.	98 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved

Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000864AM25
RA File Number	09AX04000065 AM25
Licence No and Date	0911007285/22/05/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NITAZOXANIDE(Diloxanide furoate, Cimetidine, Oxytroczone, Famotidine:)	1 kg.	1	2-Acetoxybenzoic acid	0.894 kg.
		2	5-Nitrothiazol-2-amine	0.59 kg.

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

Case No.	99 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000865AM25
RA File Number	03AX04000768 AM25
Licence No and Date	0311033991/22/05/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

MOXILEB-250DT . AMOXICILLIN TABLET 250MG.((EACH TABLET CONTAINING AMOXICILLIN TRYHYDRATE EQUIVALENT TO 250MG OF AMOXICILLIN) . NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRYHYDRATE BP (COMPACTD) - 157.850KGS (EXCLUDING 2% WASTAGE))	550000 Numbers Tablets	1	AMOXICILLIN TRYHYDRATE BP COMPACTED	160.95 kg.
MOXILEB-250 CAPSULE. AMOXICILLIN CAPSULE 250MG .(EACH CAPSULE CONTAINING AMOXICILLIN TRYHYDRATE EQUIVALENT TO 250MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRYHYDRATE BP (COMPATED)-2658.927KGS (EXCLUDING 2% WASTAGE))	9264554 Numbers Capsules	2	AMOXICILLIN TRYHYDRATE BP COMPACTED	2711.17 kg.
MOXILEB-500 CAPSULE. AMOXICILLIN CAPSULE 500MG.((EACH CAPSULE CONTAINING AMOXICILLIN TRYHYDRATE EQUIVALENT TO 500MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRYHYDRATE BP (COMPACTED) - 1722.00KGS (EXCLUDING 2% WASTAGE))	3000000 Numbers Capsules	3	AMOXICILLIN TRYHYDRATE BP COMPACTED	1755.84 kg.
MOXILEB ORAL SUSPENSION. AMOXICILLIN ORAL SUSPENSION (AMOXICILLIN SYRUP) 125MG/100ML BOTTLE ((EACH 5ML CONTAINS AMOXICILLIN TRYHYDRATE	126545 Numbers Bottles	4	AMOXICILLIN TRYHYDRATE BP COMPACTED	370.45 kg.

EQUIVALENT TO 125MG OF AMOXICILLIN). NET CONTENT OF IMPORT/EXEMPT MATERIAL USED IN EXPORT PRODUCT 1) AMOXICILLIN TRYHYDRATE BP (COMPACTED) - 363.184 KGS (EXCLUDING 2% WASTAGE))				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	100 / NC/3/MEET/Nov/202425/10
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000879AM25
RA File Number	07AX04000179 AM25
Licence No and Date	0711011361/24/05/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
RAMELTEON 8MG TABLETS	1 Number	1	RAMELTEON	8.16 mg/Tablet

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

Case No.	101 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000901AM25
RA File Number	03AX04000936 AM25
Licence No and Date	0311034124/27/05/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Percentage of export and import item with CoA.	

Case No.	102 / NC/3/MEET/Nov/202425/10										
Case Status	Case Approved										
Party Name	MAKCUR LABORATORIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024										
HQ File Number	HQRNORM APPLY 00000905AM25										
RA File Number	08AX04000290 AM25										
Licence No and Date	0811011668/27/05/2024										
Norms Committee Decision:											
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Benzathine Benzylpenicillin 1.44g (2.4MU) Injection (BENZATHINE BENZYL PENICILLIN)</td><td>1 Number</td><td>1</td><td>Benzathine Benzylpencillin Sterile BP</td><td>1.512 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Benzathine Benzylpenicillin 1.44g (2.4MU) Injection (BENZATHINE BENZYL PENICILLIN)	1 Number	1	Benzathine Benzylpencillin Sterile BP	1.512 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Benzathine Benzylpenicillin 1.44g (2.4MU) Injection (BENZATHINE BENZYL PENICILLIN)	1 Number	1	Benzathine Benzylpencillin Sterile BP	1.512 mg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	103 / NC/3/MEET/Nov/202425/10
Case Status	Case Deferred
Party Name	MELOG SPECIALITY CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024
HQ File Number	HQRNORM APPLY 00000920AM25
RA File Number	03AX04000829 AM25
Licence No and Date	0311034133/27/05/2024
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- Quantity and value of by-product i.e. Isobutylene PTBP and Polymer of butylated hydrocarbon.	

Case No.	104 / NC/3/MEET/Nov/202425/10			
Case Status	Case Approved			
Party Name	USV PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202425/ 10 and 22/11/2024			
HQ File Number	HQRNORM APPLY 00000921AM25			
RA File Number	03AX04000940 AM25			
Licence No and Date	0311034134/27/05/2024			
Norms Committee Decision:				
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

weight of Import Product = 563.091 kgs))				
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RA concerned may take further necessary action as per above decision of NC.