



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/Apr/202425/2

DATED: 30/04/2024

Please 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 also ensure compliance of SION, General Notes and Chapter Notes wherever applicable.
- V. RAs shall ensure that authorization is issued or redeemed based on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less. In this regard full compliance of the provision of Para 4.12 of FTP, Para 4.16; Para 4.21 and Para 4.51 of HBP shall be made.

Meeting No. NC/3/MEET/Apr/202425/2 dated 30/04/2024 of Norms Committee - III for the year 2024-25 was held on 30/04/2024 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 Raman Kumar, Deputy DGFT	DGFT(HQ)
2	Shri Dinesh Narain Mathur, Technical Expert	Consultant (Pharma)

3	Shri Shaish Kumar, Technical Expert	Consultant (Chemical)
4	Shri Nand Lal, Technical Expert	Consultant (Chemical)
5	Shri Uttam Dey Sarkar, ASO	DGFT (HQ)

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Apr/202425/2																
Case Status	Case Approved																
Party Name	FRESENIUS KABI ONCOLOGY LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024																
HQ File Number	018305001161AM21																
RA File Number	052304000251 AM21																
Licence No and Date	0510415659/27/10/2020																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Aug/202324/11 dated 22/08/2023 against advance authorization No. 0511000078 dated 09/12/2020 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Oxaliplatin (Assay (By HPLC on dried basis) 98% to 102%)</td><td rowspan="2">1 kg.</td><td>1</td><td>Platinum (Sponge Powder)</td><td>0.85 kg.</td></tr><tr><td>2</td><td>(1R,2R)-(-)-1,2-Diamino cyclo hexane.</td><td>0.49 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Oxaliplatin (Assay (By HPLC on dried basis) 98% to 102%)	1 kg.	1	Platinum (Sponge Powder)	0.85 kg.	2	(1R,2R)-(-)-1,2-Diamino cyclo hexane.	0.49 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Oxaliplatin (Assay (By HPLC on dried basis) 98% to 102%)	1 kg.	1	Platinum (Sponge Powder)	0.85 kg.													
		2	(1R,2R)-(-)-1,2-Diamino cyclo hexane.	0.49 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	2 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM REVIW00007068AM24
RA File Number	05AX04001017 AM23
Licence No and Date	0511013648/07/07/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it has been observed that the firm has not furnished the past production/consumption of raw material certified by GST Authorities as sought by TE. Therefore, it was decided that	

a team from CLA, New Delhi will audit the production and consumption data of the firm and submit the report to DGFT HQ within fifteen days of uploading of Minutes of Meeting on DGFT website.

Case No.	3 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM REVIW00007056AM24
RA File Number	05AX04001011 AM23
Licence No and Date	0511013749/13/07/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
3-DIFLUOROMETHYL-1-METHYL-1H-PYRAZOLE-4-CARBOXYLIC ACID	1 kg.	1	DIMETHYL FORMAMIDE	0.950 kg.
		2	Sodium Methoxide Powder	0.670 kg.
		3	ACETONITRILE	0.520 kg.
		4	TRI ETHYL AMINE (TEA)	0.350 kg.
		5	TOLUENE	0.315 kg.
		6	MIXED HEXANES	0.236 kg.
		7	N-BUTANOL	0.010 kg.
		8	Hydrazine Hydrate (100%)	0.668 kg.

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

Case No.	4 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM REVIW00008055AM24
RA File Number	05AX04001704 AM23
Licence No and Date	0511014859/16/09/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
3-PYRIDINECARBOXYLIC ACID, 2- [(2METHOXYETHOXY) METHYL]-6- (TRIFLUOROMETHYL)-ETHYL ESTER	1 kg.	1	METHOXY-AA TECH. 12 [GB]	0.820 kg.
		2	TOLUENE	0.270 kg.
		3	TRI ETHYL AMINE (TEA)	0.140 kg.
		4	Potassium Carbonate - Powder	0.020 kg.
		5	ETHYL VINYL ETHER	0.330 kg.
		6	ACETIC ACID	0.030 kg.
		7	ORTHOXYLENE	0.140 kg.

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

Case No.	5 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00003172AM23
RA File Number	03AX04003088 AM23
Licence No and Date	0311017943/16/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Oct/202223/11 dated 31/10/2022** against advance authorization **No. 0310838842 dated 13/10/2020** , 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.
1,3 DIMETHYLOL-5,5-DIMETHYL HYDANTOIN((DMDM HYDANTOIN 52%-55%) ASSAY 55% MAX BELGUARD DMDMH)	1 kg.	1	5,5 DIMETHYL HYDANTOIN ASSAY 99% MIN COLOUR PURE WHITE	0.382 kg.

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

Case No.	6 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM REVIW00007058AM24
RA File Number	05AX04002096 AM23
Licence No and Date	0511015534/31/10/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DIFLUORO METHANE SULPHONYL CHLORIDE	32,000 kg.	1	BENZYL DIFLUOROMETHYL SULPHIDE	3577.6 kg.
		2	BENZYL MERCAPTAN	39125.0 kg.
		3	OPEN HEAD DRUM 210 LITER WITH COMPOSITE 117 LITER DRUM INSIDE (MULLER SWITZERLAND)	Relevant, as per packing policy and General Notes.

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

Case No.	7 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM REVIW00007919AM24
RA File Number	05AX04002217 AM23
Licence No and Date	0511015715/09/11/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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1-(5-ACETYL-[1,4,5] OXADIAZEPAN-4-YL)-ETHANONE	1 kg.	1	HYDRAZINE HYDRATE (80%)	0.56 kg.
		2	ACETIC ANHYDRIDE	1.90 kg.
		3	Potassium Carbonate - Powder	0.94 kg.
		4	2,2'-Dichlorodiethyl ether (DCEE)	1.50 kg.
		5	DIMETHYL SULFOXIDE (DMSO)	1.30 kg.
		6	CAUSTIC POTASH LYE (POTASSIUM HYDROXIDE 95 PERCENT)	0.72 kg.
		7	N-PENTANOL	0.10 kg.

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

Case No.	8 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00005387AM23
RA File Number	05AX04002796 AM23
Licence No and Date	0511016607/28/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	9 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	COHANCE LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00005417AM23
RA File Number	09AX04000884 AM23
Licence No and Date	0911004233/29/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jan/202324/20 dated 18/01/2024** against advance authorization **No. 0911003424 dated 01/08/2022** , 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.
Isosorbide Mononitrate Extended-Relesed Tablets USP 30-MG(Each Extended-Released Tablets Contains : Diluted ISMN (40 Percent Diluted With Lactose Monohydate) USP Equivelent to ISMN 30Mg.	1 Number	1	IS5MN 60 % -LACTOSE 200 G 40% (Isosorbide Mononitrate 60 % and Lactose 40 %)	50.90 mg.

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

Case No.	10 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	COHANCE LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00005432AM23
RA File Number	09AX04000883 AM23
Licence No and Date	0911004235/30/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jan/202324/20 dated 18/01/2024** against advance authorization **No. 0911003424 dated 01/08/2022** , 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.
Isosorbide Mononitrate Extended-Relesed Tablets USP 120-MG(Each Extended Released Tablets Contains : Diluted ISMN (40% Diluted With Lactose Monohydate) USP Equivelent to ISMN 120Mg .	1 Number	1	IS5MN 60%-LACTOSE 200 G 40% (Isosorbide Mononitrate 60% and Lactose 40%)	203.60 mg.

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

Case No.	11 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	ANUH PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00006763AM23
RA File Number	03AX04005850 AM23
Licence No and Date	0311021914/06/03/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Deflazacort IP/BP/EP	1 kg.	1	11 B, 16B)-HYDROXY 2-METHLY-5H-PREGNA-	1.00 kg.

			1.4DIENO (17.16D) OXAzole-3.0-dione (D5)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	12 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	JUBILANT GENERICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001227AM24
RA File Number	05AX04000591 AM24
Licence No and Date	0511019120/01/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Levetiracetam 500 mg tablets	1 Tablet	1	Levetiracetam	510 mg/tablet
Levetiracetam 1000 mg tablets	1 Tablet	2	Levetiracetam	1020 mg/tablet

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

Case No.	13 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001233AM24

RA File Number	03AX04000925 AM24
Licence No and Date	0311024109/01/06/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Copy of Export Orders showing the product is exported to US.	

Case No.	14 / NC/3/MEET/Apr/202425/2																			
Case Status	Case Approved																			
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024																			
HQ File Number	HQRNORM APPLY 00001234AM24																			
RA File Number	09AX04000845 AM23																			
Licence No and Date	0911005139/01/06/2023																			
Norms Committee Decision:																				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																				
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="4">GCLE(7-PHENYLACETAMIDEO-3-CHLOROMETHYL CEPHALOSPORANIC ACID PARA METHOXY BENZYL ESTER) (WHITE CRYSTALLINE)</td><td rowspan="4">1 kg.</td><td>1</td><td>PENICILLIN G POTASSIUM FIRST CRYSTAL</td><td>1.3125 kg.</td></tr><tr><td>2</td><td>ACETONE</td><td>1.971 kg.</td></tr><tr><td>3</td><td>METHYLENE CHLORIDE MDC</td><td>3.29 kg.</td></tr><tr><td>4</td><td>2 MERCAPTO BENZO THIAZOLE MBT</td><td>0.511 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	GCLE(7-PHENYLACETAMIDEO-3-CHLOROMETHYL CEPHALOSPORANIC ACID PARA METHOXY BENZYL ESTER) (WHITE CRYSTALLINE)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.3125 kg.	2	ACETONE	1.971 kg.	3	METHYLENE CHLORIDE MDC	3.29 kg.	4	2 MERCAPTO BENZO THIAZOLE MBT	0.511 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
GCLE(7-PHENYLACETAMIDEO-3-CHLOROMETHYL CEPHALOSPORANIC ACID PARA METHOXY BENZYL ESTER) (WHITE CRYSTALLINE)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.3125 kg.																
		2	ACETONE	1.971 kg.																
		3	METHYLENE CHLORIDE MDC	3.29 kg.																
		4	2 MERCAPTO BENZO THIAZOLE MBT	0.511 kg.																

		5	METHANOL	1.971 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	15 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	VINYL PRODUCTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001243AM24
RA File Number	05AX04000373 AM24
Licence No and Date	0511019135/01/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Dec/202324/19 dated 05/01/2024** against advance authorization **No. 0511016621 dated 29/12/2022** , 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.
PVC Plasticizer (Phthalic, Non-Polymeric)	1 kg.	1	Phthalic Anhydride	0.400 kg.
		2	2 Ethyl Hexanol	0.700 kg.

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

Case No.	16 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	SHREE GANESH REMEDIES LIMITED
Meeting Number	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024

and Date	
HQ File Number	HQRNORM APPLY 00001244AM24
RA File Number	34AX04000140 AM24
Licence No and Date	3411003769/01/06/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis. Details of indigenous input with quantity.	

Case No.	17 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001246AM24
RA File Number	09AX04000952 AM23
Licence No and Date	0911005147/01/06/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Complete technical details as per Annexure to Appendix 4E for chemical products. Production / consumption data for the last three years duly certified by CA.	

Case No.	18 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024			
HQ File Number	HQRNORM APPLY 00001247AM24			
RA File Number	09AX04000097 AM24			
Licence No and Date	0911005137/01/06/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Case No.	19 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001248AM24
RA File Number	09AX04000181 AM24
Licence No and Date	0911005153/01/06/2023
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Bivalirudin for Injection 250mg /Vial	1 Number	1	Bivalirudin	275 mg / vial

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

Case No.	20 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001270AM24
RA File Number	34AX04000147 AM24
Licence No and Date	3411003773/02/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
POMELO ACETAL((6,6-Dimethoxy-2,5,5-trimethylhex- 2-ene))	1 kg.	1	2-Methyl-3-butene-2- ol	0.616 kg.
		2	Tri Methyl Ortho formate	0.71 kg.
		3	Iso Butyraldehyde	1.105 kg.

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

Case No.	21 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001257AM24
RA File Number	03AX04000921 AM24
Licence No and Date	0311024140/02/06/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Copy of Export Orders showing the product is exported to US.	

Case No.	22 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001260AM24
RA File Number	03AX04000922 AM24
Licence No and Date	0311024145/02/06/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete chemical reactions, Molecular weight and percentage yield on molar basis. Production/Consumption data for the last three years duly certified by CA.	

Case No.	23 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001261AM24
RA File Number	03AX04000895 AM24
Licence No and Date	0311024147/02/06/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete chemical reactions, Molecular weight and percentage yield on molar basis.	

Case No.	24 / NC/3/MEET/Apr/202425/2															
Case Status	Case Approved															
Party Name	ALEMBIC PHARMACEUTICALS LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024															
HQ File Number	HQRNORM APPLY 00001267AM24															
RA File Number	34AX04000158 AM24															
Licence No and Date	3411003772/02/06/2023															
Norms Committee Decision:																
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Glycopyrrolate injection USP 0.2 mg - 1 ml</td><td>1 Number</td><td>1</td><td>Glycopyrrolate USP</td><td>0.22 mg.</td></tr><tr><td>Glycopyrrolate injection USP 0.2 mg - 2 ml</td><td>1 Number</td><td>2</td><td>Glycopyrrolate USP</td><td>0.44 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Glycopyrrolate injection USP 0.2 mg - 1 ml	1 Number	1	Glycopyrrolate USP	0.22 mg.	Glycopyrrolate injection USP 0.2 mg - 2 ml	1 Number	2	Glycopyrrolate USP	0.44 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Glycopyrrolate injection USP 0.2 mg - 1 ml	1 Number	1	Glycopyrrolate USP	0.22 mg.												
Glycopyrrolate injection USP 0.2 mg - 2 ml	1 Number	2	Glycopyrrolate USP	0.44 mg.												

Glycopyrrolate injection USP 0.2 mg- 5 ml	1 Number	3	Glycopyrrolate USP	1.10 mg.
Glycopyrrolate injection USP 0.2 mg - 20 ml	1 Number	4	Glycopyrrolate USP	4.20 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	25 / NC/3/MEET/Apr/202425/2										
Case Status	Case Approved										
Party Name	BEST VALUE CHEM PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024										
HQ File Number	HQRNORM APPLY 00001271AM24										
RA File Number	34AX04000149 AM24										
Licence No and Date	3411003774/02/06/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No. 3411001553 dated 17/12/2021 , 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:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>PHENOXYETHYL ISOBUTYRATE (Phenoxy) ethyl 2-methylpropanoate)</td><td>1 kg.</td><td>1</td><td>ISOBUTYRIC ACID</td><td>0.5633 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PHENOXYETHYL ISOBUTYRATE (Phenoxy) ethyl 2-methylpropanoate)	1 kg.	1	ISOBUTYRIC ACID	0.5633 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
PHENOXYETHYL ISOBUTYRATE (Phenoxy) ethyl 2-methylpropanoate)	1 kg.	1	ISOBUTYRIC ACID	0.5633 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	26 / NC/3/MEET/Apr/202425/2													
Case Status	Case Approved													
Party Name	BEST VALUE CHEM PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024													
HQ File Number	HQRNORM APPLY 00001273AM24													
RA File Number	34AX04000150 AM24													
Licence No and Date	3411003775/02/06/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Nov/202324/14 dated 09/11/2023 against advance authorization No. 3411000984 dated 17/08/2021 , 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Limbunile(3,7-Dimethyl-2(3), 6-nonadienonitrile))</td><td rowspan="2">1 kg.</td><td>1</td><td>Ethyl Heptenone</td><td>1.145 kg.</td></tr><tr><td>2</td><td>Cyano Acetic acid</td><td>1.75 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Limbunile(3,7-Dimethyl-2(3), 6-nonadienonitrile))	1 kg.	1	Ethyl Heptenone	1.145 kg.	2	Cyano Acetic acid	1.75 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Limbunile(3,7-Dimethyl-2(3), 6-nonadienonitrile))	1 kg.	1	Ethyl Heptenone	1.145 kg.										
		2	Cyano Acetic acid	1.75 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	27 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	AARTI PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001283AM24
RA File Number	03AX04000485 AM24
Licence No and Date	0311024202/05/06/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	28 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001296AM24
RA File Number	05AX04000632 AM24
Licence No and Date	0511019178/05/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Budesonide Suspension For Inhalation , 0.125 mg / ml (2 ml Ampoule)	8700000 Numbers	1	Budesonide	2.284 kg.
Budesonide Suspension For Inhalation , 0.25 mg / ml (2 ml Ampoule)	10800000 Numbers	2	Budesonide	5.670 kg.
Budesonide Suspension For Inhalation , 0.5 mg / ml (2 ml Ampoule)	2400000 Numbers	3	Budesonide	2.52 kg.

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

Case No.	29 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001297AM24
RA File Number	34AX04000152 AM24

Licence No and Date	3411003779/05/06/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Aldehyde C10 (Capric Aldehyde)	1 kg.	1	Fatty Alcohol C10 (98% purity)	1.40 kg.
RA concerned may take further necessary action as per above decision of NC and also check the percentage content of item at the time of export.				

Case No.	30 / NC/3/MEET/Apr/202425/2			
Case Status	Case Approved			
Party Name	KusuMa PharMa			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024			
HQ File Number	HQRNORM APPLY 00001300AM24			
RA File Number	03AX04000899 AM24			
Licence No and Date	0311024234/05/06/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
E.D.T.A. DI SODIUM (PURE/AR)	1 kg.	1	EDTA ACID	0.80 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	31 / NC/3/MEET/Apr/202425/2										
Case Status	Case Approved										
Party Name	AURA PHARMACEUTICALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024										
HQ File Number	HQRNORM APPLY 00001303AM24										
RA File Number	03AX04000739 AM24										
Licence No and Date	0311024240/05/06/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Aug/202324/11 dated 22/08/2023 against advance authorization No. 0311009243 dated 07/12/2021 , 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:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>ARGYROL 1% /SILVER VITELLINATE NASAL DROPS 1% weight by volume</td><td>1 Number</td><td>1</td><td>SILVER VITELLINATE</td><td>102.00 mg /10 ml. Vial</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ARGYROL 1% /SILVER VITELLINATE NASAL DROPS 1% weight by volume	1 Number	1	SILVER VITELLINATE	102.00 mg /10 ml. Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
ARGYROL 1% /SILVER VITELLINATE NASAL DROPS 1% weight by volume	1 Number	1	SILVER VITELLINATE	102.00 mg /10 ml. Vial							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	32 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001348AM24
RA File Number	08AX04000333 AM24
Licence No and Date	0811008323/06/06/2023
Norms Committee Decision:	

The Committee considered the case as per agenda and it has been observed that the export item is new type of drug delivery system and there is no standard wastage. For such export, wastage applied by the firm is 127.22% for import item No. (1) and 126.73% for import item No. (2) which appears to be very high. Therefore, it was decided to call the firm for attending **Personal Hearing** before Norms Committee to explain its case along with relevant documents, i.e. PPT, Plant Operation Video etc.

Case No.	33 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	INTIGREAT CONSULTING SERVICES LLP
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001324AM24
RA File Number	03AX04000737 AM24
Licence No and Date	0311024265/06/06/2023

Norms Committee Decision:

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

- 1. No specific import item is given. Please get the specific import item endorsed in the License.**
- 2. Copy of Drug Manufacturing License (DML) with approved composition.**
- 3. Copy of Master Batch Formula.**
- 4. Why 5% overages is required in the export. Any such approval from Drug Authorities?**

Case No.	34 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	SHILPA PHARMA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001330AM24
RA File Number	07AX04000315 AM24
Licence No and Date	0711007735/06/06/2023

Norms Committee Decision:

The case is under consideration for want of comments of TE.

Case No.	35 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001340AM24
RA File Number	03AX04000962 AM24
Licence No and Date	0311024276/06/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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	1 Number	7	Carbamazepine	408.00 mg.

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.		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.	36 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	LOZEN PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001379AM24
RA File Number	03AX04001008 AM24
Licence No and Date	0311024330/07/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Approved composition of each export item from Drug Licensing Authority. 2. Copy of Master-Batch Formula for each export item. 3. Chemical description / Catalogue for import item No. (4).	

Case No.	37 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001382AM24
RA File Number	03AX04001033 AM24
Licence No and Date	0311024333/07/06/2023
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Apr/202425/2 dated 30/04/2024** against advance authorization **No. 0311024333 dated 07/06/2023** , 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.
YAPOX CL 30/10 "HYDROQUINONE BIS" (2 HYDROXY ETHYL ETHER)	1 kg.	1	HYDROQUINONE	0.735 kg.
		2	ETHYLENE CARBONATE	1.232 kg.

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

Case No.	38 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001384AM24
RA File Number	03AX04001034 AM24
Licence No and Date	0311024337/07/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Mar/202324/26 dated 22/03/2024** against advance authorization **No. 0311030426 dated 24/01/2024** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
OCTYLATED DIPHENYLAMINE (OCD FLAKES/POWDER)	1 kg.	1	DIPHENYLAMINE	0.405 kg.
		2	DI ISOBUTYLENE	0.622 kg.

		3	ACTIVATED CLAY	0.100 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	39 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001424AM24
RA File Number	05AX04000664 AM24
Licence No and Date	0511019264/09/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Mar/202324/26 dated 22/03/2024** against advance authorization **No. 0511016407 dated 15/12/2022** , 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.
DI OCTYL TERA PHTHALATE (DOTP)	1 kg.	1	PURE TERA PHTHALIC ACID	0.447 kg.
		2	2 ETHYL HEXANOL	0.680 kg.

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

Case No.	40 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024

and Date	
HQ File Number	HQRNORM APPLY 00001425AM24
RA File Number	03AX04000550 AM24
Licence No and Date	0311024389/09/06/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Copy of Export Orders showing the product is exported to US.	

Case No.	41 / NC/3/MEET/Apr/202425/2															
Case Status	Case Approved															
Party Name	TORRENT PHARMACEUTICALS LTD															
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024															
HQ File Number	HQRNORM APPLY 00001432AM24															
RA File Number	08AX04000386 AM24															
Licence No and Date	0811008360/09/06/2023															
Norms Committee Decision:																
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>CLOZAPINE TABLETS 25 MG (ZIPROC 25 MG)</td><td>1 Number</td><td>1</td><td>CLOZAPINE BP</td><td>25.50 mg/Tablet</td></tr><tr><td>CLOZAPINE TABLETS 100 MG (ZIPROC 100 MG)</td><td>1 Number</td><td>2</td><td>CLOZAPINE BP</td><td>102.00 mg/Tablet</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CLOZAPINE TABLETS 25 MG (ZIPROC 25 MG)	1 Number	1	CLOZAPINE BP	25.50 mg/Tablet	CLOZAPINE TABLETS 100 MG (ZIPROC 100 MG)	1 Number	2	CLOZAPINE BP	102.00 mg/Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
CLOZAPINE TABLETS 25 MG (ZIPROC 25 MG)	1 Number	1	CLOZAPINE BP	25.50 mg/Tablet												
CLOZAPINE TABLETS 100 MG (ZIPROC 100 MG)	1 Number	2	CLOZAPINE BP	102.00 mg/Tablet												
RA concerned may take further necessary action as per above decision of NC.																

Case No.	42 / NC/3/MEET/Apr/202425/2													
Case Status	Case Approved													
Party Name	SENTISS PHARMA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024													
HQ File Number	HQRNORM APPLY 00001433AM24													
RA File Number	05AX04000661 AM24													
Licence No and Date	0511019270/09/06/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Kombinil-DUO Eye/Ear Drops 5ml Vial</td><td>2777778 Vials</td><td>1</td><td>Dexamethasone Micronised PH EUR USP JP</td><td>14.167 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Kombinil-DUO Eye/Ear Drops 5ml Vial	2777778 Vials	1	Dexamethasone Micronised PH EUR USP JP	14.167 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Kombinil-DUO Eye/Ear Drops 5ml Vial	2777778 Vials	1	Dexamethasone Micronised PH EUR USP JP	14.167 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	43 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001437AM24
RA File Number	03AX04000985 AM24
Licence No and Date	0311024401/09/06/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Mometasone Furoate & Azelastine HCL Nasal Spray (150MD) / (DIRNELID AZ) 150 MDI / Momate AZ NASAL SPRAY 150 MDI((Each Spray Delivers 140mcg of Azelastine HCL)	1 Number	1	Azelastine Hydrochloride BP	0.02142 gm
Mometasone Furoate & Azelastine HCL Nasal Spray (150MD) / (DIRNELID AZ) 150 MDI / Momate AZ NASAL SPRAY 150 MDI((Each Spray Delivers 140mcg of Azelastine HCL)	1 Number	2	Azelastine Hydrochloride BP	0.02142 gm.
Mometasone Furoate & Azelastine HCL Nasal Spray (75MD) / (DIRNELID AZ) 75 MDI / Momate AZ NASAL SPRAY 75 MDI((Each Spray Delivers 140mcg of Azelastine HCL)	1 Number	3	Azelastine Hydrochloride BP	0.01071 gm.

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

Case No.	44 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001454AM24
RA File Number	34AX04000148 AM24
Licence No and Date	3411003799/09/06/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/May/202324/5 dated 08/06/2023 against advance authorization No. 3411000701 dated 08/06/2021, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
VERDYL ISOBUTYRATE((3a,4,5,6,7a-hexahydro-4,7-methano-1H-inden-5-yl isobutyrate))	1 kg.	1	Dicyclopentadiene	0.705 kg.
		2	Iso butyric Acid	0.493 kg.

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

Case No.	45 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	UNIMAX LABORATORIES
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001505AM24
RA File Number	05AX04000673 AM24
Licence No and Date	0511019298/12/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Drug Manufacturing License (DML) showing approved composition of each export item. 2. Certificate of Analysis (CoA) for import item No.3 and 4 from foreign supplier showing actual potency.	

Case No.	46 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001486AM24
RA File Number	05AX04000711 AM24
Licence No and Date	0511019290/12/06/2023
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Sep/202324/13 dated 14/09/2023** against advance authorization **No. 0510404862 dated 12/12/2017**, 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.
PVC PLASTICIZER (DINP)	1 kg.	1	PHTHALIC ANHYDRIDE	0.372 kg.
		2	ISO NONANOL	0.726 kg.

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

Case No.	47 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001573AM24
RA File Number	03AX04001075 AM24
Licence No and Date	0311024511/13/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Master-Batch Formula for each export item. 2. Certificate of Analysis (CoA) of import item.	

Case No.	48 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001530AM24
RA File Number	03AX04001109 AM24
Licence No and Date	0311024473/13/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No. 0311022762 dated 12/04/2023**, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Benzydamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and(all other flavours. Each lozenge contains (i) Benzydamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride- 1.33mg (iii) Isomalt ST-M – 2586 mg.	1000 Numbers	1	Benzydamine Hydrochloride	3.06 gm
		2	Cetylpyridinium Chloride	1.356 gm
		3	Isomalt ST-M	2586.00 gm
Benzydamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti- Inflammatory,(Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg.	1000 Numbers	4	Benzydamine Hydrochloride	3.06 gm
		5	Isomalt ST-M	2586.00 gm
Benzydamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free.(Each lozenge contains (i) Benzydamine Hydrochloride- 3mg (ii) Isomalt ST-M - 2586mg.	1000 Numbers	6	Benzydamine Hydrochloride	3.06 gm
		7	Isomalt ST-M	2586.00 gm
Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg.	1000 Numbers	8	Cetylpyridinium Chloride	1.356 gm
		9	Isomalt ST-M	2586.00 gm

Cetylpyridinium Chloride And Benzydamine Hydrochloride Antiseptic Lozenges Sugar Free.(Each lozenge contains (i) Cetylpyridinium Chloride- 1 mg (ii) Isomalt ST-M - 2586mg.	1000 Numbers	10	Cetylpyridinium Chloride	1.02 gm
		11	Isomalt ST-M	2586.00 gm

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

Case No.	49 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001546AM24
RA File Number	03AX04001142 AM24
Licence No and Date	0311024489/13/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete technical details as per Annexure to Appendix-4E.	

Case No.	50 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001555AM24
RA File Number	03AX04001141 AM24
Licence No and Date	0311024501/13/06/2023
Norms Committee Decision:	

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

Complete technical details as per Annexure to Appendix-4E.

Case No.	51 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001556AM24
RA File Number	03AX04001157 AM24
Licence No and Date	0311024502/13/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete technical details as per Annexure to Appendix-4E.	

Case No.	52 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001557AM24
RA File Number	03AX04001137 AM24
Licence No and Date	0311024503/13/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:-	

Complete technical details as per Annexure to Appendix-4E.

Case No.	53 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001558AM24
RA File Number	03AX04001150 AM24
Licence No and Date	0311024504/13/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete technical details as per Annexure to Appendix-4E.	

Case No.	54 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001562AM24
RA File Number	03AX04001138 AM24
Licence No and Date	0311024507/13/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete technical details as per Annexure to Appendix-4E.	

Case No.	55 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001564AM24
RA File Number	03AX04001139 AM24
Licence No and Date	0311024508/13/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete technical details as per Annexure to Appendix-4E.	

Case No.	56 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001565AM24
RA File Number	03AX04001169 AM24
Licence No and Date	0311024509/13/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete technical details as per Annexure to Appendix-4E.	

Case No.	57 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	CHEMIKER PHARMACEUTICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001572AM24
RA File Number	50AX04000015 AM24
Licence No and Date	5011000916/13/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete technical details as per Annexure to Appendix-4E.	

Case No.	58 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001574AM24
RA File Number	03AX04001083 AM24
Licence No and Date	0311024513/13/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Copy of Master-Batch Formula for each export item.	

Case No.	59 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001580AM24
RA File Number	03AX04001140 AM24
Licence No and Date	0311024530/14/06/2023

Norms Committee Decision:

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

Copy of Export Orders showing the product is exported to US.

Case No.	60 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001586AM24
RA File Number	03AX04001174 AM24
Licence No and Date	0311024536/14/06/2023

Norms Committee Decision:

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

Complete technical details as per Annexure to Appendix-4E.

Case No.	61 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001587AM24
RA File Number	03AX04001170 AM24
Licence No and Date	0311024537/14/06/2023

Norms Committee Decision:

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

Complete technical details as per Annexure to Appendix-4E.

Case No.	62 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001594AM24
RA File Number	03AX04001153 AM24
Licence No and Date	0311024542/14/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- i. Complete chemistry with Molecular weight and percentage of yield on molar basis. ii. End-use of export product.	

Case No.	63 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001595AM24
RA File Number	03AX04001154 AM24
Licence No and Date	0311024543/14/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete technical details as per Annexure to Appendix-4E.	

Case No.	64 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001629AM24
RA File Number	03AX04001202 AM24
Licence No and Date	0311024559/15/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- i. Complete chemistry with molecular weight and percentage yield on molar basis. ii. End use of export product.	

Case No.	65 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001634AM24
RA File Number	34AX04000189 AM24
Licence No and Date	3411003805/15/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Copy of Master-Batch Formula for each export items, showing net content of inputs in the export items.	

Case No.	66 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved

Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001659AM24
RA File Number	03AX04001231 AM24
Licence No and Date	0311024593/15/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Mar/202324/26 dated 22/03/2024** against advance authorization **No. 0311031086 dated 12/02/2024**, 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.
Atorvastatin Calcium Tablets USP 10mg.	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.4415 mg.
		2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg.
		3	Calcium Acetate	18.049 mg.
		4	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy and General Notes.
Atorvastatin Calcium Tablets USP 20 mg.	1 Number Tablet	5	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg.
		6	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427 mg.
		7	Calcium Acetate	36.090 mg.
		8	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy and General Notes.
Atorvastatin Calcium Tablets USP 40mg.	1 Number Tablet	9	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg.

		10	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08 mg.
		11	Calcium Acetate	71.963 mg.
		12	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy and General Notes.
Atorvastatin Calcium Tablets USP 80mg.	1 Number Tablet	13	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg.
		14	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg.
		15	Calcium Acetate	144.929 mg.
		16	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy and General Notes.

Note: The above norms are valid only for subject to fulfillment of following conditions:-

- 1. Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application).**
- 2. Export to USA only.**
- 3. Firm holding Certificate of Manufacturing Exclusivity.**

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

Case No.	67 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001722AM24
RA File Number	08AX04000457 AM24
Licence No and Date	0811008434/16/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Mar/202324/26 dated 22/03/2024** against advance authorization **No. 0811010634 dated 01/02/2024**, 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.
Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)	1 Number	1	Tranexamic acid	1.05 gm/100 ml Vial

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

Case No.	68 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ARCH PROTECTION CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001705AM24
RA File Number	03AX04001182 AM24
Licence No and Date	0311024600/16/06/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	69 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	VINYL PRODUCTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001723AM24
RA File Number	05AX04000743 AM24
Licence No and	0511019402/16/06/2023

Date																	
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Dec/202324/19 dated 05/01/2024 against advance authorization No. 0511016621 dated 29/12/2022, 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"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">PVC PLASTICIZER (PLASTICIZER, NON-POLLYMERIC)</td> <td rowspan="2">1 kg.</td> <td>1</td> <td>PHTHALIC ANHYDRIDE</td> <td>0.400 kg.</td> </tr> <tr> <td>2</td> <td>2 ETHYL HEXANOL</td> <td>0.700 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PVC PLASTICIZER (PLASTICIZER, NON-POLLYMERIC)	1 kg.	1	PHTHALIC ANHYDRIDE	0.400 kg.	2	2 ETHYL HEXANOL	0.700 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
PVC PLASTICIZER (PLASTICIZER, NON-POLLYMERIC)	1 kg.	1	PHTHALIC ANHYDRIDE	0.400 kg.													
		2	2 ETHYL HEXANOL	0.700 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	70 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	CONNEX PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001735AM24
RA File Number	26AX04000033 AM24
Licence No and Date	2611000980/16/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Stage wise and overall yield of the reaction. 2. Complete justification of low yield of the reaction. 3. Stoichiometric material balance on molar basis.	

Case No.	71 / NC/3/MEET/Apr/202425/2
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Case Status	Case Approved										
Party Name	MICRO LABS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024										
HQ File Number	HQRNORM APPLY 00001884AM24										
RA File Number	07AX04000372 AM24										
Licence No and Date	0711008298/19/06/2023										
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="196 678 1428 970"> <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>AZELASTINE HYDROCHLORIDE EYE DROPS SOLUTION 0.05% weight by volume.</td><td>1 Number</td><td>1</td><td>AZELASTINE HYDROCHLORIDE Ph.Eur</td><td>5.10 mg /10 ml vial</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.	AZELASTINE HYDROCHLORIDE EYE DROPS SOLUTION 0.05% weight by volume.	1 Number	1	AZELASTINE HYDROCHLORIDE Ph.Eur	5.10 mg /10 ml vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
AZELASTINE HYDROCHLORIDE EYE DROPS SOLUTION 0.05% weight by volume.	1 Number	1	AZELASTINE HYDROCHLORIDE Ph.Eur	5.10 mg /10 ml vial							

Case No.	72 / NC/3/MEET/Apr/202425/2					
Case Status	Case Approved					
Party Name	R.L.FINE CHEM PRIVATE LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024					
HQ File Number	HQRNORM APPLY 00001885AM24					
RA File Number	07AX04000378 AM24					
Licence No and Date	0711008301/19/06/2023					
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Sep/202223/8 dated 23/09/2022 against advance authorization No. 0711001517 dated 20/07/2021, 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:- <table border="1" data-bbox="196 1911 1428 2007"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.		

MECLIZINE HYDROCHLORIDE (IP/USP/BP)	1 kg.	1	3 METHYL BENZYL CHLORIDE	0.391 kg.
		2	TOLUENE	Not shown in process
		3	ACETONE	1.65 kg.

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

Case No.	73 / NC/3/MEET/Apr/202425/2										
Case Status	Case Approved										
Party Name	MICRO LABS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024										
HQ File Number	HQRNORM APPLY 00001886AM24										
RA File Number	07AX04000371 AM24										
Licence No and Date	0711008304/19/06/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No. 0811010831 dated 21/02/2024 , 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><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML</td><td>1 Number</td><td>1</td><td>TRANEXAMIC ACID USP</td><td>1.05 gm/100 ml Vial</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML	1 Number	1	TRANEXAMIC ACID USP	1.05 gm/100 ml Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML	1 Number	1	TRANEXAMIC ACID USP	1.05 gm/100 ml Vial							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	74 / NC/3/MEET/Apr/202425/2													
Case Status	Case Deferred													
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024													
HQ File Number	HQRNORM APPLY 00001889AM24													
RA File Number	03AX04001069 AM24													
Licence No and Date	0311024666/19/06/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBI 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>NAPROLAT-CARBOPLATIN BP 10 MG/ML INJ.(1x45ML) 450 MG.</td><td>1 Number Vial</td><td>1</td><td>Carboplatin IP/ BP/ USP</td><td>472.50 mg. /45 ml. Injection.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	NAPROLAT-CARBOPLATIN BP 10 MG/ML INJ.(1x45ML) 450 MG.	1 Number Vial	1	Carboplatin IP/ BP/ USP	472.50 mg. /45 ml. Injection.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
NAPROLAT-CARBOPLATIN BP 10 MG/ML INJ.(1x45ML) 450 MG.	1 Number Vial	1	Carboplatin IP/ BP/ USP	472.50 mg. /45 ml. Injection.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	75 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001892AM24
RA File Number	09AX04000025 AM24
Licence No and Date	0911005223/19/06/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No. 0911006753 dated 14/02/2024 , 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.
GCLE(7-PHENYLACETAMIDEO-3-CHLOROMETHYL CEPHALOSPORANIC ACID PARA METHOXY BENZYL ESTER) (WHITE CRYSTALLINE)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.3125 kg.
		2	ACETONE	1.971 kg.
		3	METHYLENE CHLORIDE MDC	3.29 kg.
		4	2 MERCAPTO BENZO THIAZOLE MBT	0.511 kg.
		5	METHANOL	1.971 kg.

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

Case No.	76 / NC/3/MEET/Apr/202425/2			
Case Status	Case Approved			
Party Name	GLENMARK PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024			
HQ File Number	HQRNORM APPLY 00001905AM24			
RA File Number	03AX04001262 AM24			
Licence No and Date	0311024672/19/06/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBI Vol. I as per details given below or as applied by the firm, whichever is less:-				

Clindamycin Phosphate Foam 1%, 50 gm	13889 Numbers	2	Clindamycin Phosphate USP	7.08 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	77 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001954AM24
RA File Number	03AX04001227 AM24
Licence No and Date	0311024688/20/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No. 0311022762 dated 12/04/2023**, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Benzydamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and(all other flavours. Each lozenge contains (i) Benzydamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride-1.33mg (iii) Isomalt ST-M - 2586mg.	1000 Number	1	Benzydamine Hydrochloride	3.06 gm.
		2	Cetylpyridinium Chloride	1.356 gm.
		3	Isomalt ST-M	2586.00 gm.
Benzydamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-Bacterial Lozenges Sugar Free. Each	1000 Number	4	Benzydamine Hydrochloride	3.06 gm.
		5	Isomalt ST-M	2586.00 gm.

lozenge contains (i) Benzydamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg.				
Benzydamine Hydrochloride Anti- Inflammatory Lozenges Sugar Free.(Each lozenge contains (i) Benzydamine Hydrochloride- 3mg (ii) Isomalt ST-M - 2586mg.	1000 Number	6	Benzydamine Hydrochloride	3.06 gm.
		7	Isomalt ST-M	2586.00 gm
Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg.	1000 Number	8	Cetylpyridinium Chloride	1.356 gm
		9	Isomalt ST-M	2586.00 gm
Cetylpyridinium Chloride And Benzydamine Hydrochloride Antiseptic Lozenges Sugar Free.(Each lozenge contains (i) Cetylpyridinium Chloride- 1 mg (ii) Isomalt ST-M - 2586mg.	1000 Number	10	Cetylpyridinium Chloride	1.02 gm.
		11	Isomalt ST-M	2586.00 gm

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

Case No.	78 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00001953AM24
RA File Number	03AX04001254 AM24
Licence No and Date	0311024687/20/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No. 0311022762 dated 12/04/2023**, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Benzydamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and(all other flavours. Each lozenge contains (i) Benzydamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride-1.33mg (iii) Isomalt ST-M - 2586mg.	1000 Number	1	Benzydamine Hydrochloride	3.06 gm.
		2	Cetylpyridinium Chloride	1.356 gm.
		3	Isomalt ST-M	2586.00 gm.
Benzydamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg.	1000 Number	4	Benzydamine Hydrochloride	3.06 gm.
		5	Isomalt ST-M	2586.00 gm.
Benzydamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free.(Each lozenge contains (i) Benzydamine Hydrochloride- 3mg (ii) Isomalt ST-M - 2586mg.	1000 Number	6	Benzydamine Hydrochloride	3.06 gm.
		7	Isomalt ST-M	2586.00 gm
Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg.	1000 Number	8	Cetylpyridinium Chloride	1.356 gm
		9	Isomalt ST-M	2586.00 gm

Cetylpyridinium Chloride And Benzydamine Hydrochloride Antiseptic Lozenges Sugar Free.(Each lozenge contains (i) Cetylpyridinium Chloride- 1 mg (ii) Isomalt ST-M - 2586mg.	1000 Number	10	Cetylpyridinium Chloride	1.02 gm.
		11	Isomalt ST-M	2586.00 gm

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

Case No.	79 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00002051AM24
RA File Number	08AX04000505 AM24
Licence No and Date	0811008459/22/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
IMIPENEM AND CILASTATIN FOR INJECTION USP/BP/IP/CEP/EP/ChP 500MG	1 Number	1	Sterile Mixture of Imipenem and Cilastatin for Injection	1.102 gm.

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

Case No.	80 / NC/3/MEET/Apr/202425/2										
Case Status	Case Approved										
Party Name	CITO CHEM INDUSTRIES PVT.LTD.										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024										
HQ File Number	HQRNORM APPLY 00002066AM24										
RA File Number	56AX04000189 AM24										
Licence No and Date	5611001972/22/06/2023										
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Sep/202324/14 dated 27/09/2023 against advance authorization No. 0811008785 dated 18/07/2023, 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" data-bbox="196 857 1428 1045"> <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>Clobetasol Propionate</td><td>1 kg.</td><td>1</td><td>Betamethasone</td><td>1.00 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.	Clobetasol Propionate	1 kg.	1	Betamethasone	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Clobetasol Propionate	1 kg.	1	Betamethasone	1.00 kg.							

Case No.	81 / NC/3/MEET/Apr/202425/2					
Case Status	Case Approved					
Party Name	MICRO LABS LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024					
HQ File Number	HQRNORM APPLY 00002068AM24					
RA File Number	07AX04000426 AM24					
Licence No and Date	0711008352/22/06/2023					
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="196 1882 1428 1977"> <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.		

BROMOCRIPTIN TABLETS 2.5MG [Each Tablet contains Bromocriptin Mesylate equivalent to Bromocriptin 2.5 mg.]	1 Number	1	BROMOCRIPTIN MESYLATE BP/EP/IP/USP	2.924 mg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	82 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00002077AM24
RA File Number	34AX04000200 AM24
Licence No and Date	0311024778/22/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 5 gm Tube	1200000 Numbers	1	Lidocaine USP	152.80 kg.
		2	Prilocaine Base USP	152.80 kg.
Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 30 gm tube	475000 Numbers	3	Lidocaine USP	363.30 kg.
		4	Prilocaine Base USP	363.30 kg.
Lidocaine Ointment USP 5% 30 gm tube	5000 Numbers	5	Lidocaine USP	7.64 kg.
Lidocaine Ointment USP 5% 35.44 gm tube	5000 Numbers	6	Lidocaine USP	9.01 kg.

Lidocaine Ointment USP 5% 50 gm Jar	5000 Numbers	7	Lidocaine USP	12.74 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	83 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	ALKEM LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00002078AM24
RA File Number	03AX04001302 AM24
Licence No and Date	0311024779/22/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Venlafaxine Hydrochloride Extended Release Tablets 37.5 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 37.5mg.	1 Number	1	Venlafaxine Hydrochloride USP	43.127 mg.
Venlafaxine Hydrochloride Extended Release Tablets 75 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 75 mg.	1 Number	2	Venlafaxine Hydrochloride USP	84.00 mg.
Venlafaxine Hydrochloride Extended Release Tablets 150 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 150 mg.	1 Number	3	Venlafaxine Hydrochloride USP	166.50 mg.
Venlafaxine Hydrochloride Extended Release	1 Number	4	Venlafaxine Hydrochloride	247.50 mg.

Tablets 225 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 225mg.			USP	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	84 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	RUMIT LIFE CARE
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00002087AM24
RA File Number	03AX04001180 AM24
Licence No and Date	0311024787/22/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Betamethasone Dipropionate IP/BP/EP/USP	1 kg.	1	Betamethasone IP/BP/EP/USP	0.868 kg.

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

Case No.	85 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00002100AM24

RA File Number	03AX04001224 AM24
Licence No and Date	0311024798/22/06/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Complete chemical reactions with Molecular and Structural Formula and Molecular weight along with stage wise percentage yields on molar basis. 2. Material Balance (Stoichiometric Balance details) for the entire manufacturing process.	

Case No.	86 / NC/3/MEET/Apr/202425/2																
Case Status	Case Approved																
Party Name	PAYAL POLYPLAST PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024																
HQ File Number	HQRNORM APPLY 00002099AM24																
RA File Number	05AX04000823 AM24																
Licence No and Date	0511019494/22/06/2023																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Sep/202425/13 dated 14/09/2023 against advance authorization No. 0510404862 dated 12/12/2017 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">PVC PLASTICIZER (PHTHALIC, NON POLYMERIC) (DINP)</td><td rowspan="2">1 kg.</td><td>1</td><td>PHTHALIC ANHYDRIDE</td><td>0.372 kg.</td></tr><tr><td>2</td><td>ISO NONANOL</td><td>0.726 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PVC PLASTICIZER (PHTHALIC, NON POLYMERIC) (DINP)	1 kg.	1	PHTHALIC ANHYDRIDE	0.372 kg.	2	ISO NONANOL	0.726 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
PVC PLASTICIZER (PHTHALIC, NON POLYMERIC) (DINP)	1 kg.	1	PHTHALIC ANHYDRIDE	0.372 kg.													
		2	ISO NONANOL	0.726 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	87 / NC/3/MEET/Apr/202425/2										
Case Status	Case Approved										
Party Name	GLOBAL CALCIUM PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024										
HQ File Number	HQRNORM APPLY 00002158AM24										
RA File Number	07AX04000433 AM24										
Licence No and Date	0711008370/23/06/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jan/202324/21 dated 24/01/2024 against advance authorization No. 0711009399 dated 10/10/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Nifuroxazide</td><td>1 kg.</td><td>1</td><td>5-Nitro-2-furohydrazide</td><td>0.634</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Nifuroxazide	1 kg.	1	5-Nitro-2-furohydrazide	0.634
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Nifuroxazide	1 kg.	1	5-Nitro-2-furohydrazide	0.634							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	88 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00002558AM24
RA File Number	07AX04000359 AM24
Licence No and Date	0711008395/26/06/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:-	

1. **Step wise manufacturing process.**
2. **Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.**
3. **Material balance (Stoichiometric Balance details) for the entire manufacturing process.**
4. **Justification for low yield along with published literature.**
5. **Past production / consumption data for last two years duly certified by GST.**
6. **Authentic technical literature/catalogue in support of percentage yield claimed in the entire manufacturing process.**

Case No.	89 / NC/3/MEET/Apr/202425/2
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00002491AM24
RA File Number	03AX04001286 AM24
Licence No and Date	0311024864/26/06/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Copy of Export Orders showing the product is exported to US.	

Case No.	90 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00004844AM24
RA File Number	03AX04001874 AM24
Licence No and Date	0311026010/04/08/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/24 dated 05/03/2024 against advance authorization No.0311014263 dated 29/04/2022, 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.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

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

Case No.	91 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00004845AM24
RA File Number	03AX04001880 AM24
Licence No and Date	0311026011/04/08/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/24 dated 05/03/2024** against advance authorization **No.0311014263 dated 29/04/2022**, 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.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

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

Case No.	92 / NC/3/MEET/Apr/202425/2										
Case Status	Case Approved										
Party Name	HARMAN FINOCHEM LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024										
HQ File Number	HQRNORM APPLY 00005165AM24										
RA File Number	03AX04002258 AM24										
Licence No and Date	0311026486/22/08/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/24 dated 05/03/2024 against advance authorization No.0311014263 dated 29/04/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed</th></tr><tr><td>Sacubitril+Calcium (Sacubitril Calcium)</td><td>1 kg.</td><td>1</td><td>2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)</td><td>1.237 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed							
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	93 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00005192AM24
RA File Number	03AX04002292 AM24
Licence No and Date	0311026535/23/08/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/24 dated 05/03/2024 against advance authorization	

No.0311014263 dated 29/04/2022, 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.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

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

Case No.	94 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00005188AM24
RA File Number	03AX04002257 AM24
Licence No and Date	0311026528/23/08/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/24 dated 05/03/2024** against advance authorization **No.0311014263 dated 29/04/2022**, 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.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

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

Case No.	95 / NC/3/MEET/Apr/202425/2										
Case Status	Case Approved										
Party Name	HARMAN FINOCHEM LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024										
HQ File Number	HQRNORM APPLY 00005187AM24										
RA File Number	03AX04002259 AM24										
Licence No and Date	0311026527/23/08/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/24 dated 05/03/2024 against advance authorization No.0311014263 dated 29/04/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed</th></tr><tr><td>Sacubitril+Calcium (Sacubitril Calcium)</td><td>1 kg.</td><td>1</td><td>2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)</td><td>1.237 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed							
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	96 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00005776AM24
RA File Number	03AX04002663 AM24
Licence No and Date	0311027253/21/09/2023
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/24 dated 05/03/2024** against advance authorization **No.0311014263 dated 29/04/2022**, 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.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

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

Case No.	97 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00005777AM24
RA File Number	03AX04002664 AM24
Licence No and Date	0311027255/21/09/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/24 dated 05/03/2024** against advance authorization **No.0311014263 dated 29/04/2022**, 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.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

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

Case No.	98 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00005775AM24
RA File Number	03AX04002665 AM24
Licence No and Date	0311027252/21/09/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/24 dated 05/03/2024** against advance authorization **No.0311014263 dated 29/04/2022**, 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.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

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

Case No.	99 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00006420AM24
RA File Number	03AX04003262 AM24
Licence No and Date	0311028121/23/10/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/24 dated 05/03/2024** against advance authorization **No.0311014263 dated 29/04/2022**, 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.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl) amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

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

Case No.	100 / NC/3/MEET/Apr/202425/2
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202425/ 2 and 30/04/2024
HQ File Number	HQRNORM APPLY 00008643AM24
RA File Number	05AX04003613 AM24
Licence No and Date	0511024042/19/02/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Apr/202425/1 dated 10/04/2024** against advance authorization **No.0510415972 dated 24/11/2020**, 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.
HFC-134a (HYDROFLUOROCARBAN 1,1,1,2-TETRAFLUOROETHANE)	1 kg.	1	TCE (TRICHLORO ETHYLENE)	2.116 kg.
		2	ACID GRADE FLUORSPAR	1.065 kg.

		3	EMPTY CANS 340 G	Relevant, as per Packing Policy and General Notes
		4	CAPS FOR EMPTY CANS / TINPLATE CAP 1/2 inch	Relevant, as per Packing Policy and General Notes

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