



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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

(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Jan/202324/21

DATED: 24/01/2024

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.

Meeting No. NC/3/MEET/Jan/202324/21 dated 24/01/2024 of Norms Committee - III for the year 2023-24 was held on 24/01/2024 under the Chairmanship of Rajiv Soni ,Joint 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 2015-20.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	UTTAM SARKAR,Assistant Section Officer	DGFT(HQ)
2	Raman Kumar,Deputy DGFT	DGFT(HQ)
3	NAND Lal,Technical Consultant	DPIIT
4	SHAISH KUMAR,Technical Consultant	DGFT
5	DINESHNARAIN MATHUR,Technical Consultant	DGFT
6	Nand Lal,Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	INNOVASSYNTH TECHNOLOGIES (INDIA) LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00004451AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	2 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007476AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents from the firm:- Catalogue for import item 3 & 4. Master Batch Formula showing net content of inputs in the export.	

Case No.	3 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007891AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The case is under consideration for want of comments from Deptt. of Bio-Technology.	

Case No.	4 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	AETHER INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM REVIW00008030AM24			
RA File Number	522104000061 AM20			
Licence No and Date	5210043148/14/08/2019			
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.
4-BROMOMETHYL-2-CYANOBIHENYL	1 kg.	1	2-CHLOROBENZOIC ACID	Not required
		2	2-CHLOROBENZONITRILE	1.235 kg.
		3	PARA CHLOROTOLUENE	1.340 kg.
		4	TETRAHYDROFURAN	1.00 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	5 / NC/3/MEET/Jan/202324/21				
Case Status	Case Approved				
Party Name	AETHER INDUSTRIES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024				
HQ File Number	HQRNORM REVIW00008019AM24				
RA File Number	522404000044 AM20				
Licence No and Date	5210043258/12/12/2019				
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.
ORTHO TOLYL BENZO NITRILE		1 kg.	1	PARA CHLORO TOLUENE	1.340 kg.

		2	TETRAHYDROFURAN	1.00 kg.
		3	2-CHLOROBENZONITRILE	1.235 kg.

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

Case No.	6 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00002221AM23
RA File Number	07AX04000559 AM23
Licence No and Date	0711004755/23/07/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- To give chemical reaction of the process.	

Case No.	7 / NC/3/MEET/Jan/202324/21																
Case Status	Case Approved																
Party Name	ARCH PROTECTION CHEMICALS PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024																
HQ File Number	HQRNORM APPLY 00006341AM23																
RA File Number	03AX04004385 AM23																
Licence No and Date	0311021465/15/02/2023																
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="2">BIT 84 PERCENTAGE 400KG BB IN 1-2 Benzisothiazoline-3-One (Net Content 0.974 kg and 2.273 kg respectively)</td><td rowspan="2">1 kg.</td><td>1</td><td>2- CHLOROBENZ ONITRILE</td><td>0.968 kg.</td></tr><tr><td>2</td><td>SODIUM METHYL MERCAPTIDE 20%</td><td>2.418 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	BIT 84 PERCENTAGE 400KG BB IN 1-2 Benzisothiazoline-3-One (Net Content 0.974 kg and 2.273 kg respectively)	1 kg.	1	2- CHLOROBENZ ONITRILE	0.968 kg.	2	SODIUM METHYL MERCAPTIDE 20%	2.418 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
BIT 84 PERCENTAGE 400KG BB IN 1-2 Benzisothiazoline-3-One (Net Content 0.974 kg and 2.273 kg respectively)	1 kg.	1	2- CHLOROBENZ ONITRILE	0.968 kg.													
		2	SODIUM METHYL MERCAPTIDE 20%	2.418 kg.													

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

Case No.	8 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000742AM24
RA File Number	08AX04000208 AM24
Licence No and Date	0811008135/10/05/2023

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. 0811008079 dated 03/05/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PROPAFENONE HYDROCHLORIDE TABLETS 150 MG(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 150 MG)	1 Number	1	PROPAFENONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR.	153 mg/tablet
PROPAFENONE HYDROCHLORIDE TABLETS 300 MG(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 300 MG [IN WHICH ACTIVE INGREDIENT PROPAFENONE HYDROCHLORIDE USED IS 48.000 KGS.])	1 Number	2	PROPAFENONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR.	306 mg/tablet

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

Case No.	9 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000743AM24

RA File Number	08AX04000207 AM24
Licence No and Date	0811008136/10/05/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	10 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	MEDICLONE HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000746AM24
RA File Number	04AX04000118 AM24
Licence No and Date	0411005383/10/05/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	11 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000768AM24
RA File Number	07AX04000187 AM24
Licence No and Date	0711007535/11/05/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Justification for higher wastage (400.8%) in manual. 2. Master Batch Formula (MBF) certified by Q.C. In-charge.	

Case No.	12 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	SATYADEVA PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000775AM24
RA File Number	09AX04000090 AM24
Licence No and Date	0911005025/11/05/2023

Norms Committee Decision:

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

Case No.	13 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000782AM24
RA File Number	03AX04000570 AM24
Licence No and Date	0311023542/12/05/2023

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. 0311022327 dated 21/03/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CHLORAMPHENICOL EYE DROPS 10 ML((EACH VIAL CONTAINS CHLORAMPHENICOL MICRONIZED 0.050GM NET WT OF BULK DRUG IS 15.95 KGS))	1 Number	1	CHLORAMPHENICOL MICRONIZED	51.00 mg/vial

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

Case No.	14 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000789AM24
RA File Number	09AX04000030 AM24
Licence No and Date	0911005027/12/05/2023

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. 0911004841 dated 19/04/2023**, 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.
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				allowed.
(2R,3R,4R,5S,6S)-2-(acetoxymethyl)-6-(4-chloro-3-(4-ethoxybenzyl)phenyl)tetrahydro-2H-pyran-3,4,5-triyl Triacetate (Diloxanide furoate, Cimetidine, Oxytrocyanide, Famotidine: Other)	1 kg	1	5-Bromo-2-chlorobenzoic Acid	1.105 kg.
		2	Trimethyl silyl chloride	2.60 kg.
		3	(3R,4S,5S,6R)-3,4,5-Trihydroxy-6-(hydroxy methyl) tetrahydro-2H-pyran-2-one (THO)/Glucono-Delta-Lactone	0.707 kg.
		4	Triethyl silane	2.11 kg.
		5	Tetra hydro furan	5.00 kg.
		6	Ethyl phenyl ether/Phenetole	0.707 kg.
		7	n-Methylmorpholine	3.00 kg.

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

Case No.	15 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000802AM24
RA File Number	07AX04000198 AM24
Licence No and Date	0711007559/12/05/2023

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. 0711004103 dated 26/05/2022**, 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.
PHLOROGLUCINOL 160 MG OD TABLETS	1 Number	1	PHLOROGLUCINOL DIHYDRATE Ph.Eur	163.20 mg.

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

Case No.	16 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000803AM24
RA File Number	07AX04000199 AM24
Licence No and Date	0711007560/12/05/2023

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.
COLCHICINE 0.6MG CAPSULES (0.90 KG)	1500010 Numbers	1	COLCHICINE USP	0.9 kg.

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

Case No.	17 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000807AM24
RA File Number	30AX04000059 AM24
Licence No and Date	3011003543/12/05/2023

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.
DEXKETOPROFEN TROMETAMOL	1 kg.	1	KETOPROFEN	1.00 kg.
		2	N OCTYL D GLUCAMINE	0.36 kg.

		3	TRIS AMINO BUFFER TROMETHAMINE	0.36 kg.
		4	ETHYL ACETATE	1.00 kg.

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

Case No.	18 / NC/3/MEET/Jan/202324/21													
Case Status	Case Approved													
Party Name	MICRO LABS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024													
HQ File Number	HQRNORM APPLY 00001093AM24													
RA File Number	NA													
Licence No and Date	0711007560/12/05/2023													
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>COLCHICINE 0.6MG CAPSULES (0.90 KG)</td><td>1500010 Numbers</td><td>1</td><td>COLCHICINE USP</td><td>0.9 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	COLCHICINE 0.6MG CAPSULES (0.90 KG)	1500010 Numbers	1	COLCHICINE USP	0.9 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
COLCHICINE 0.6MG CAPSULES (0.90 KG)	1500010 Numbers	1	COLCHICINE USP	0.9 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	19 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000836AM24
RA File Number	08AX04000216 AM24
Licence No and Date	0811008181/15/05/2023
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/202324/17 dated 20/12/2023 against advance authorization No. 0811004069 dated 15/02/2022 , 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.
BUSPIRONE HYDROCHLORIDE TABLETS USP 5 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 5 MG)	1 Number	1	BUSPIRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR.	5.1 mg / tablet
BUSPIRONE HYDROCHLORIDE TABLETS USP 7.5 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 7.5 MG)	1 Number	2	BUSPIRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR.	7.65 mg / tablet
BUSPIRONE HYDROCHLORIDE TABLETS USP 10 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 10 MG)	1 Number	3	BUSPIRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR.	10.2 mg / tablet
BUSPIRONE HYDROCHLORIDE TABLETS USP 15 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 15 MG)	1 Number	4	BUSPIRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR.	15.3 mg / tablet
BUSPIRONE HYDROCHLORIDE TABLETS USP 30 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 30 MG [IN WHICH ACTIVE INGREDIENT BUSPIRONE HYDROCHLORIDE USED IS 98.100 KGS.])	1 Number	5	BUSPIRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR.	30.6 mg / tablet

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

Case No.	20 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	ANUH PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000838AM24
RA File Number	03AX04000593 AM24
Licence No and Date	0311023591/15/05/2023

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. **3/82-ALC4/2020 dated 07/08/2020** against advance authorization No. **0310831894 dated 27/09/2019**, 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.
Triamcinolone Acetonide IP/BP/USP/EP	1 kg.	1	9 11B-Epoxidetriamcinolone(5TR)	1.00 kg.

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

Case No.	21 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000842AM24
RA File Number	08AX04000116 AM24
Licence No and Date	0811008184/15/05/2023

Norms Committee Decision:

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

- To give molecular weight of both reactants and products indicating yield of reaction.**
- Stoichiometric Material balance of the reaction.**
- End use of export item.**

Case No.	22 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	SHIVA BIO CHEM INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000845AM24
RA File Number	50AX04000007 AM24
Licence No and Date	5011000884/15/05/2023

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.
Sunflower Lecithin (Liquid)	1 MT	1	Crude Sunflower Lecithin Liquid	1.01 MT

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

Case No.	23 / NC/3/MEET/Jan/202324/21																			
Case Status	Case Approved																			
Party Name	ASCENT FINECHEM PRIVATE LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024																			
HQ File Number	HQRNORM APPLY 00000849AM24																			
RA File Number	08AX04000108 AM24																			
Licence No and Date	0811008186/15/05/2023																			
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 NC/3/MEET/Dec/202324/17 dated 20/12/2023 against advance authorization No. 0810145127 dated 30/04/2019 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																				
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="3">N-(3-AMINOPROPYL) IMIDAZOLE WHITE OR OFF WHITE CRYSTAL</td><td rowspan="3">1 kg.</td><td>1</td><td>IMIDAZOLE</td><td>0.712 kg.</td></tr><tr><td>2</td><td>SODIUM METHOXIDE POWDER</td><td>1.00 kg.</td></tr><tr><td>3</td><td>ACRYLONITRILE</td><td>0.500 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	N-(3-AMINOPROPYL) IMIDAZOLE WHITE OR OFF WHITE CRYSTAL	1 kg.	1	IMIDAZOLE	0.712 kg.	2	SODIUM METHOXIDE POWDER	1.00 kg.	3	ACRYLONITRILE	0.500 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
N-(3-AMINOPROPYL) IMIDAZOLE WHITE OR OFF WHITE CRYSTAL	1 kg.	1	IMIDAZOLE	0.712 kg.																
		2	SODIUM METHOXIDE POWDER	1.00 kg.																
		3	ACRYLONITRILE	0.500 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	24 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000850AM24
RA File Number	34AX04000113 AM24
Licence No and Date	3411003716/15/05/2023
Norms Committee Decision:	

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

Case No.	25 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	AVA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000858AM24
RA File Number	03AX04000650 AM24
Licence No and Date	0311023611/16/05/2023

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. 2/82-ALC4/2018 dated 16/05/2018** against advance authorization **No. 0310810275 dated 03/01/2017**, 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.
ZINC DIAMMONIUM EDTA (LIQUID) - Zinc Content 9% (? 1)	1 kg.	1	ETHYLENE DIAMINE TETRA ACETIC ACID	0.422 kg.

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

Case No.	26 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	AVA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000859AM24
RA File Number	NA
Licence No and Date	0311023611/16/05/2023

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. 2/82-ALC4/2018 dated 16/05/2018** against advance authorization **No. 0310810275 dated 03/01/2017**, 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.
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ZINC DIAMMONIUM EDTA (LIQUID) - Zinc Content 9% (? 1)	1 kg.	1	ETHYLENE DIAMINE TETRA ACETIC ACID	0.422 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	27 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	SARAL CHEMTECH LLP
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000865AM24
RA File Number	33AX04000105 AM23
Licence No and Date	3311001206/16/05/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	28 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	MAXCURE NUTRAVEDICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000872AM24
RA File Number	05AX04000388 AM24
Licence No and Date	0511018844/16/05/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	29 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000876AM24
RA File Number	08AX04000284 AM24
Licence No and Date	0811008214/16/05/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	30 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000884AM24
RA File Number	05AX04000392 AM24
Licence No and Date	0511018851/17/05/2023

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 **NC/3/MEET/Nov/202324/16 dated 17/11/2023** against advance authorization **No. 0511013171 dated 13/06/2022**, 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.
Tobramycin 300mg / 5 ml Nebuliser Solution ((Each ml contains Tobramycin Ph. Eur. 60 mg) (Equivalent to 504.000 Kg of Bulk Drug))	1 Number	1	Tobramycin	306 mg.

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

Case No.	31 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	SANDOZ PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000890AM24
RA File Number	03AX04000516 AM24
Licence No and Date	0311023636/17/05/2023

Norms Committee Decision:

The committee considered the case as per agenda and it was decided to fix ad-hoc norms as per SION A-412.

Case No.	32 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000891AM24
RA File Number	03AX04000467 AM24
Licence No and Date	0311023637/17/05/2023

Norms Committee Decision:

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

Sl. No	Export Product	Quantity
1	Azelaic Acid 15% Gel 50 Gm (Medical Creams & Ointments)	1 Number

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

Note:

- i. 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**
- ii. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**
- iii. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	33 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	AMINES AND PLASTICIZERS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000892AM24
RA File Number	03AX04000417 AM24
Licence No and Date	0311023638/17/05/2023

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. 0311008443 dated 11/11/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Methyl-Monoethanolamine (MMEA)	1 kg.	1	Ethylene Oxide	0.6453 kg.
		2	Monomethyl Amine 40%	0.4257 kg.

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

Case No.	34 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000897AM24
RA File Number	05AX04000410 AM24
Licence No and Date	0511018871/17/05/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Get the license amended to show content of API in the export product as per DML.	

Case No.	35 / NC/3/MEET/Jan/202324/21				
Case Status	Case Approved				
Party Name	ALEMBIC PHARMACEUTICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024				
HQ File Number	HQRNORM APPLY 00000905AM24				
RA File Number	34AX04000124 AM24				
Licence No and Date	3411003726/17/05/2023				
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/202223/14 dated 07/12/2022 against advance authorization No. 3411001604 dated 29/12/2021 , 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:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.

Duloxetine Caps.20 mg(Duloxetine Caps.20 mg (Net content of active ingredients 60.000 kgs))	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	22.88 mg
		2	Sugar Spheres (30-35 PHARM-A-SPHERES)	20.33 mg
		3	Hypromellose (Pharmacoat 606)	20.00 mg
		4	Talc (Luzenac Pharma Ultra Micronised grade)	12.63 mg
		5	Sucrose (Compressuc PS)	15.67 mg
		6	Hypromellose Phthalate (HP 55)	12.07 mg
		7	Triethyl Citrate	1.21 mg
Duloxetine Caps. 30 mg(Duloxetine Caps. 30 mg (Net content of active ingredients 210.00 kgs))	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	34.36 mg
		2	Sugar Spheres (30-35 PHARM-A-SPHERES)	30.50 mg
		3	Hypromellose (Pharmacoat 606)	30.00 mg
		4	Talc (Luzenac Pharma Ultra Micronised grade)	18.94 mg
		5	Sucrose (Compressuc PS)	23.50 mg
		6	Hypromellose Phthalate (HP 55)	18.10 mg
		7	Triethyl Citrate	1.81 mg
Duloxetine Caps. 40 mg(Duloxetine Caps. 40 mg (Net content of active ingredients 120.00 kgs))	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	45.76 mg

ingredients 120.000 kgs))		2	Sugar Spheres (30-35 PHARM-A-SPHERES)	40.67 mg
		3	Hypromellose (Pharmacoat 606)	40.00 mg
		4	Talc (Luzenac Pharma Ultra Micronised grade)	25.26 mg
		5	Sucrose (Compressuc PS)	31.34 mg
		6	Hypromellose Phthalate (HP 55)	24.14 mg
		7	Triethyl Citrate	2.41 mg
Duloxetine Caps. 60 mg(Duloxetine Caps. 60 mg (Net content of active ingredients 450.00 kgs))	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	68.71 mg
		2	Sugar Spheres (30-35 PHARM-A-SPHERES)	61.00 mg
		3	Hypromellose (Pharmacoat 606)	60.00 mg
		4	Talc (Luzenac Pharma Ultra Micronised grade)	37.88 mg
		5	Sucrose (Compressuc PS)	47.00 mg
		6	Hypromellose Phthalate (HP 55)	36.20 mg
		7	Triethyl Citrate	3.62 mg

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

Case No.	36 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred

Party Name	AZAKEM LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000910AM24
RA File Number	09AX04000127 AM24
Licence No and Date	0911005042/17/05/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	37 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000920AM24
RA File Number	08AX04000086 AM24
Licence No and Date	0811008233/18/05/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	38 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	SENTISS PHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00000947AM24			
RA File Number	05AX04000412 AM24			
Licence No and Date	0511018894/18/05/2023			
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 NC/3/MEET/Sep/202324/14 dated 27/09/2023 against advance authorization No. 0511019932 dated 19/07/2023 , 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:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml	1 Vial	1	Brinzolamide Micronized Sterile	51.00 mg / vial

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

Case No.	39 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000949AM24
RA File Number	09AX04001044 AM23
Licence No and Date	0911005057/18/05/2023

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.
S-(+)-2-2-AMINO BUTANAMIDE HYDROCHLORIDE (CARBOXYAMIDE-FUNCTION COMPOUNDS; AMIDE-FUNCTION COMPOUNDS OF CARBONIC ACID - ACYCLIC AMIDES (INCLUDING ACYCLIC CARBAMATES) AND THEIR DERIVATIVES; SALTS THEREOF : OTHER.)	1 kg.	1	Propionaldehyde	1.65 kg.
		2	Sodium cyanide	1.176 kg.
		3	L-Tartaric acid	0.875 kg.

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

Case No.	40 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	AARTI PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000955AM24
RA File Number	03AX04000342 AM24
Licence No and Date	0311023698/18/05/2023

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 **NC/3/MEET/Oct/202122/9 dated 15/10/2021** against advance authorization **No. 0310838954 dated 16/10/2020**, 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.
BUDESONIDE	1 kg	1	16 ALPHA HYDROXY PREDNISOLONE	0.972 kg.

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

Case No.	41 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000956AM24
RA File Number	04AX04000143 AM24
Licence No and Date	0411005437/18/05/2023

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 **NC/3/MEET/Jan/202324/20 dated 18/01/2024** against advance authorization **No. 0411005354 dated 08/05/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
IBUPROFEN	1 kg.	1	ISOBUTYL ACETOPHENONE	1.110 kg.
		2	SODIUM METAL	0.235 kg.
		3	MONOCHLORO ACETIC ACID	0.919 kg.
		4	ISO PROPYL ALCOHOL	0.50 kg.
		5	SODIUM DICHROMATE	0.630 kg.

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

Case No.	42 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000957AM24
RA File Number	04AX04000142 AM24
Licence No and Date	0411005438/18/05/2023

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 **NC/3/MEET/Jan/202324/20 dated 18/01/2024** against advance authorization **No. 0411005354 dated 08/05/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
IBUPROFEN	1 kg.	1	ISOBUTYL ACETOPHENONE	1.110 kg.
		2	SODIUM METAL	0.235 kg.
		3	MONOCHLORO ACETIC ACID	0.919 kg.
		4	ISO PROPYL ALCOHOL	0.50 kg.
		5	SODIUM DICHROMATE	0.630 kg.

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

Case No.	43 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000959AM24
RA File Number	03AX04000603 AM24
Licence No and Date	0311023701/18/05/2023

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided

by the firm, it was decided to revise ad-hoc norms for export to US only are as under:-

Sl. No	Export Product	Quantity
1	Medical Ointment cream Gel(Clotrimazole and Betamethasone Dipropionate Cream USP 1% 0.05% 15 Gm (Tot wt 2941.16 Kgs Poly 66.18 Kgs, white petro 441.17 Kgs, Min oil 176.47, cetyl 148.23, Stearyl 63.48Kgs, beta1.88 Kgs, Clotri 29.41 Kgs, Benzyl 29.41Kgs, Tube 196077 Nos))	1 Number
2	Name: Medical ointment cream, Gel(Clotrimazole and Betamethasone Dipropionate Cream USP 1% 0.05% 45 Gm (Tot wt 2941.11 Kgs Poly 66.17 Kgs, white petro 441.17 Kgs, Min oil176.47, cetyl 148.23, Stearyl 63.48Kgs, beta 1.88 Kgs, Clotri 29.41 Kgs, Benzyl 29.41 Kgs, Tube 65358 Nos))	1 Number

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

Note:

- i. 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**
- ii. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**
- iii. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	44 / NC/3/MEET/Jan/202324/21
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Case Status	Case Approved																
Party Name	BEST VALUE CHEM PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024																
HQ File Number	HQRNORM APPLY 00000963AM24																
RA File Number	34AX04000010 AM24																
Licence No and Date	3411003731/18/05/2023																
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. 3411001750 dated 04/02/2022, 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="3">Undecavertol (Kakdinol)((4-Methyl-3-decen- 5-ol))</td><td rowspan="3">1 kg.</td><td>1</td><td>Propionaldehyde</td><td>0.947 kg.</td></tr> <tr> <td>2</td><td>1-Pentanol / N Amyl Alcohol</td><td>0.709 kg.</td></tr> <tr> <td>3</td><td>Magnesium Turning</td><td>0.182 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.	Undecavertol (Kakdinol)((4-Methyl-3-decen- 5-ol))	1 kg.	1	Propionaldehyde	0.947 kg.	2	1-Pentanol / N Amyl Alcohol	0.709 kg.	3	Magnesium Turning	0.182 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Undecavertol (Kakdinol)((4-Methyl-3-decen- 5-ol))	1 kg.	1	Propionaldehyde	0.947 kg.													
		2	1-Pentanol / N Amyl Alcohol	0.709 kg.													
		3	Magnesium Turning	0.182 kg.													

Case No.	45 / NC/3/MEET/Jan/202324/21													
Case Status	Case Approved													
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024													
HQ File Number	HQRNORM APPLY 00000978AM24													
RA File Number	09AX04000132 AM24													
Licence No and Date	0911005072/19/05/2023													
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"> <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">Dolutegravir Sodium</td><td rowspan="2">1 kg.</td><td>1</td><td>(R)-3-AMINO-1-BUTANOL</td><td>0.395 kg.</td></tr> <tr> <td>2</td><td>2,4-DIFLUOROBENZYLAMINE</td><td>0.426 kg.</td></tr> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Dolutegravir Sodium	1 kg.	1	(R)-3-AMINO-1-BUTANOL	0.395 kg.	2	2,4-DIFLUOROBENZYLAMINE	0.426 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Dolutegravir Sodium	1 kg.	1	(R)-3-AMINO-1-BUTANOL	0.395 kg.										
		2	2,4-DIFLUOROBENZYLAMINE	0.426 kg.										

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

Case No.	46 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	JUBILANT GENERICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000989AM24
RA File Number	05AX04000389 AM24
Licence No and Date	0511018912/19/05/2023

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. **0311026693 dated 29/08/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Amantadine HCL Tablet 100mg	1 Number	1	Amantadine Hydrochloride	102 mg/tablet

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

Case No.	47 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00000995AM24
RA File Number	03AX04000744 AM24
Licence No and Date	0311023755/20/05/2023

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. **3/82-ALC4/2019 dated 05/07/2019** against advance authorization No. **0310826001 dated 28/12/2018**, 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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2, 6-Dichloro Benzoyl chloride	1 kg.	1	2,6-Dichloro Benzaldehyde	0.927 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	48 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00001008AM24
RA File Number	03AX04000694 AM24
Licence No and Date	0311023767/22/05/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents from the firm.	

Case No.	49 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	AQUA VITOE LABORATORIES			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00001013AM24			
RA File Number	30AX04000068 AM24			
Licence No and Date	3011003557/22/05/2023			
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 NC/3/MEET/Jun/202223/5 dated 08/07/2022 against advance authorization No. 0811001842 dated 25/06/2021 , 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.
Ceftazidime for Injection U.S.P 1.0 gm	1 Number	1	Ceftazidime	1100.00 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	50 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00001033AM24
RA File Number	03AX04000403 AM24
Licence No and Date	0311023793/23/05/2023

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 **NC/3/MEET/Mar/202223/22 dated 24/03/2023** against advance authorization **No. 0311019737 dated 03/12/2022**, 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.
LIOTHRONINE SODIUM MCG TABLETS	51 Number	1	Liothyronine sodium	5.10 MCG per 5 MCG Tablet
LIOTHRONINE SODIUM MCG TABLETS	101 Number	2	Liothyronine sodium	10.20 MCG per 10 MCG Tablet
LIOTHRONINE SODIUM MCG TABLETS	201 Number	3	Liothyronine sodium	20.40 MCG per 20 MCG Tablet

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

Case No.	51 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	HINDYS LAB PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00001037AM24
RA File Number	09AX04001157 AM23
Licence No and Date	0911005091/23/05/2023

Norms Committee Decision:

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

Case No.	52 / NC/3/MEET/Jan/202324/21
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Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00001038AM24
RA File Number	03AX04000751 AM24
Licence No and Date	0311023797/23/05/2023

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/202324/6 dated 14/06/2023** against advance authorization **No. 0311021683 dated 24/02/2023**, 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.
BRIMONIDINE TARTRATE EYE DROPS 5ML (IOBRIM EYE DROPS 5ML) ((EACH VIAL CONTAINS BRIMONIDINE L TARTRATE 0.01 GM NET WT OF BULK DRUG IS 0.910 KGS))	1 Vial	1	BRIMONIDINE L-TARTRATE	10.2 mg / vial

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

Case No.	53 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00001039AM24
RA File Number	09AX04001152 AM23
Licence No and Date	0911005092/23/05/2023

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. 0911005377 dated 11/07/2023**, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
(R)-9-[2-phosphonomethoxy)propyl]	1 kg.	1	ADENINE	0.85 kg.

Adenine(Compounds containing a pyrimidine ring (whether or not hydrogenated) or piperazine ring in the structure)		2	N,N-DIMETHYLFORMAMIDE	2.00 kg.
		3	(R)-1,2-PROPYLENE CARBONATE	0.79 kg.
		4	N-METHYL-2-PYRROLIDONE	0.21 kg.
		5	Diethyl Para Toluene Sulfonyl Oxy Methyl Phosphonate	1.00 kg.
		6	Magnesium Tert. Butoxide	1.00 kg.

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

Case No.	54 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	FOURRTS (INDIA) LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00001041AM24
RA File Number	04AX04000154 AM24
Licence No and Date	0411005457/23/05/2023

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.
CIPROFLOXACIN TABLETS USP 500 mg(CIPROFLOXACIN TABLETS USP 500 mg (10000x100x10`s)- 10000000 Nos - 5000 KGS)	1 Number	1	CIPROFLOXACIN HYDROCHLORIDE USP	500 mg / tablet

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

Case No.	55 / NC/3/MEET/Jan/202324/21
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Case Status	Case Approved										
Party Name	SHARP MINT LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024										
HQ File Number	HQRNORM APPLY 00001045AM24										
RA File Number	05AX04000477 AM24										
Licence No and Date	0511018941/23/05/2023										
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. 0511020129 dated 31/07/2023 , 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><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Menthol Crystal</td><td>1 kg.</td><td>1</td><td>L-Menthol</td><td>1.02 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Menthol Crystal	1 kg.	1	L-Menthol	1.02 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Menthol Crystal	1 kg.	1	L-Menthol	1.02 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	56 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00001048AM24
RA File Number	08AX04000163 AM24
Licence No and Date	0811008261/23/05/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	57 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	ABHILASH LIFE SCIENCES LLP
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00001074AM24
RA File Number	32AX04000094 AM24
Licence No and Date	3211004934/24/05/2023
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. 12/82-ALC4/2018 dated 12/12/2018** against advance authorization **No. 0810142890 dated 22/06/2018**, 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.
Nitrofurantoin 50mg Capsules	1 Number	1	Nitrofurantoin Macrocrystals	51 mg / Capsule
Nitrofurantoin 100mg Capsules	1 Number	2	Nitrofurantoin Macrocrystals	102 mg / Capsule

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

Case No.	58 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	HUMAN PHARMA LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00001075AM24
RA File Number	08AX04000092 AM24
Licence No and Date	0811008267/24/05/2023

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/202122/2 dated 02/07/2021** against advance authorization **No. 0511002362 dated 30/04/2021**, 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.
DEXAMETHASONE SODIUM PHOSPHATE	1 kg.	1	16 Alpha-Methyl Epoxide (8-DM)	0.811 kg.

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

Case No.	59 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	HUMAN PHARMA LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024

HQ File Number	HQRNORM APPLY 00001076AM24													
RA File Number	08AX04000093 AM24													
Licence No and Date	0811008268/24/05/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>MOMETASONE FUROATE</td><td>1 kg.</td><td>1</td><td>16 Alpha-Methyl Epoxide (8-DM)</td><td>1.00 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MOMETASONE FUROATE	1 kg.	1	16 Alpha-Methyl Epoxide (8-DM)	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
MOMETASONE FUROATE	1 kg.	1	16 Alpha-Methyl Epoxide (8-DM)	1.00 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	60 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	HETERO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00001078AM24			
RA File Number	09AX04000108 AM24			
Licence No and Date	0911005106/24/05/2023			
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/202122/7 dated 13/08/2021 against advance authorization No. 0910066753 dated 16/10/2018 , 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.
(1S,4R)-4-AMINO-2-CYCLOPENTEN-1-METHANOL HYDROCHLORIDE (Diloxanide furoate, Cimetidine, Oxyclozanide, Famotidine: Other)	1 kg.	1	2-AZABICYCLO(2.2.1.)HEPT-5-ENE-3-ONE (VINCELACTAM)	1.337 kg.
		2	L (+)TARTARIC ACID	0.85 kg.
		3	SODIUM BORO HYDRIDE	0.214 kg.
		4	THIONYL CHLORIDE	0.40 kg.

		5	METHANOL	2.00 kg.
		6	Triethylamine	0.60 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	61 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00001081AM24
RA File Number	09AX04000106 AM24
Licence No and Date	0911005107/24/05/2023

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. 0911003371 dated 20/07/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
(S)-TERT-BUTYL-3-OXO-1-PHENYLPROPYLCARBAMATE (Diloxanide furoate, Cimetidine, Oxiclozanide, Famotidine:)	1 kg.	1	Malonic acid	4.46 kg.
		2	L (+) Tartaric acid	2.41 kg.
		3	2,2,6,6-tetramethyl piparidine-1-oxyl	0.27 kg.
		4	Thionyl Chloride	3.81 kg.
		5	Di Tert.Butyl Di Carbonate	1.57 kg.

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

Case No.	62 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved

Party Name	HETERO LABS LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024																			
HQ File Number	HQRNORM APPLY 00001082AM24																			
RA File Number	09AX04000107 AM24																			
Licence No and Date	0911005108/24/05/2023																			
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. 0911003396 dated 25/07/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="3">3-(3-ISOPROPYL-5-METHYL-4H-1,2,4-TRIAZOL-4-YL)EXO-8-AZA-BICYCLO[3.2.1] OCTANE (Diloxanide furoate, Cimetidine, Oxyclozanide, Famotidine:)</td> <td rowspan="3">1 kg.</td> <td>1</td> <td>Nortropinone.HCl</td> <td>1.88 kg.</td> </tr> <tr> <td>2</td> <td>Tetra Hydro Furan</td> <td>3.32 kg.</td> </tr> <tr> <td>3</td> <td>ACETONITRILE</td> <td>3.77 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	3-(3-ISOPROPYL-5-METHYL-4H-1,2,4-TRIAZOL-4-YL)EXO-8-AZA-BICYCLO[3.2.1] OCTANE (Diloxanide furoate, Cimetidine, Oxyclozanide, Famotidine:)	1 kg.	1	Nortropinone.HCl	1.88 kg.	2	Tetra Hydro Furan	3.32 kg.	3	ACETONITRILE	3.77 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
3-(3-ISOPROPYL-5-METHYL-4H-1,2,4-TRIAZOL-4-YL)EXO-8-AZA-BICYCLO[3.2.1] OCTANE (Diloxanide furoate, Cimetidine, Oxyclozanide, Famotidine:)	1 kg.	1	Nortropinone.HCl	1.88 kg.																
		2	Tetra Hydro Furan	3.32 kg.																
		3	ACETONITRILE	3.77 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	63 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	EMCURE PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00005336AM24
RA File Number	31AX04000151 AM24
Licence No and Date	3111002604/31/08/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	64 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	RIDDHI PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00005518AM24

RA File Number	34AX04000422 AM24			
Licence No and Date	3411004096/08/09/2023			
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.6/82-ALC4/2018 dated 26/07/2018 against advance authorization No. 3410043042 dated 20/03/2017 , 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.
1,3, DICHLORO ACETONE	1 kg.	1	1,3, DICHLORO 2- PROPANOL	1.069 kg.
		2	SODIUM DICHRIMATE	1.700 kg.

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

Case No.	65 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	DELTA FINOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00005619AM24
RA File Number	03AX04002566 AM24
Licence No and Date	0311027073/13/09/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. To give complete chemistry of reactant and product indicating molecular weight of each chemical and yield of the reaction. 2. The value of by-product if any, with evidence. 3. Stoichiometric material balance of the reaction.	

Case No.	66 / NC/3/MEET/Jan/202324/21			
Case Status	Case Deferred			
Party Name	KAVALIFE PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00005806AM24			

RA File Number	07AX04000908 AM24
Licence No and Date	0711009260/21/09/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Justification for 36% wastage. 2. Commercial value of by-product obtained 3. What kind of process loss envisaged. 4. Production/consumption data duly certified by GST for last one year.	

Case No.	67 / NC/3/MEET/Jan/202324/21													
Case Status	Case Approved													
Party Name	MANKIND PHARMA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024													
HQ File Number	HQRNORM APPLY 00005810AM24													
RA File Number	05AX04001798 AM24													
Licence No and Date	0511021104/22/09/2023													
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/Nov/202324/16 dated 17/11/2023 against advance authorization No. 0511013171 dated 13/06/2022 , 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>Tobramycin Inhalation Solution, 300mg/ 5ml (Having net content of 99.14 kg of Bulk drug)</td><td>1 Number</td><td>1</td><td>TOBRAMYCIN USP</td><td>306 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	Tobramycin Inhalation Solution, 300mg/ 5ml (Having net content of 99.14 kg of Bulk drug)	1 Number	1	TOBRAMYCIN USP	306 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed										
Tobramycin Inhalation Solution, 300mg/ 5ml (Having net content of 99.14 kg of Bulk drug)	1 Number	1	TOBRAMYCIN USP	306 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	68 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	DHANUKA LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00005878AM24			
RA File Number	05AX04001755 AM24			

Licence No and Date	0511021168/26/09/2023			
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/Dec/202324/19 dated 05/01/2024 against advance authorization No. 0511017012 dated 25/01/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TELMISARTAN USP/BP/EP/JP/IP(POWDER)	1 kg.	1	2-n-propyl-4-methyl-6-(1-methylbenzimidazol-2-yl)	0.621 kg.
		2	2-Cyano-4-Methyl Biphenyl (OTBN)	0.650 kg.
		3	Acetic Acid	0.90 kg.
		4	Toluene	1.71 kg.
		5	N-Butanol	1.34 kg.
		6	Methanol	1.25 kg.

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

Case No.	69 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	KLJ PLASTICIZERS LIMITED.			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00005900AM24			
RA File Number	05AX04001893 AM24			
Licence No and Date	0511021195/27/09/2023			
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/Jan/202122/13 dated 21/01/2022 against advance authorization No.0511004139 dated 16/08/2021, 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:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

TRI ETHYL CITRATE (TEC)(TRI ETHYL CITRATE (TEC) (PACKED IN 400 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES (3,400.000 KGS. WITHOUT WASTAGE)) (EACH DRUM SHALL WEIGHT 8.5 KG AND STORAGE CAPACITY 250.000 KGS.))	1 kg.	1	CITRIC ACID	0.726 kg.
		2	DENATURED ETHYL ALCOHOL	0.526 kg.
		3	HDPE GRANULES (TOTAL WEIGHT = 3,570.000 KGS.)	Relevant, as per packing policy

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

Case No.	70 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00005955AM24
RA File Number	34AX04000512 AM24
Licence No and Date	3411004188/29/09/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	71 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	MEGHMANI DYES AND INTERMEDIATES LLP
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00005963AM24
RA File Number	08AX04001166 AM24
Licence No and Date	0811009505/02/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	72 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024

and Date	
HQ File Number	HQRNORM APPLY 00005974AM24
RA File Number	03AX04002789 AM24
Licence No and Date	0311027510/03/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	73 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00005992AM24
RA File Number	03AX04002781 AM24
Licence No and Date	0311027528/03/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	74 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00005997AM24
RA File Number	03AX04002790 AM24
Licence No and Date	0311027534/03/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	75 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	INDIA GLYCOLS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006006AM24
RA File Number	05AX04001846 AM24
Licence No and Date	0511021178/03/10/2023
Norms Committee Decision:	

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

Case No.	76 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006014AM24
RA File Number	03AX04002949 AM24
Licence No and Date	0311027570/03/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	77 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006018AM24
RA File Number	05AX04001916 AM24
Licence No and Date	0511021302/03/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	78 / NC/3/MEET/Jan/202324/21				
Case Status	Case Approved				
Party Name	ROSSARI BIOTECH LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024				
HQ File Number	HQRNORM APPLY 00006029AM24				
RA File Number	03AX04002962 AM24				
Licence No and Date	0311027600/04/10/2023				
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.	

N-METHYL MORPHOLINE OXIDE 50 % (NMMO-50)	1 kg.	1	MORPHOLINE	0.440 kg.
		2	FORMALDEHYDE	0.1517 kg.
		3	MONO CARBOXYLIC ACID	0.25 kg.

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

Case No.	79 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	GLOBAL CALCIUM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00006126AM24			
RA File Number	07AX04001033 AM24			
Licence No and Date	0711009399/10/10/2023			
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/Dec/202324/17 dated 20/12/2023 against advance authorization No. 0711004862 dated 08/08/2022 , 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.
Nifuroxazide	1 kg.	1	5-Nitro-2-furohydrazide	0.634 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	80 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006144AM24
RA File Number	09AX04000605 AM24
Licence No and Date	0911005927/10/10/2023
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/Jun/202324/8 dated 30/06/2023** against advance authorization **No. 0911005029 dated 15/05/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Methocarbamol	1 kg.	1	Guaifenesin	1.050 kg.
		2	Sodium Methoxide Powder (SMO)	0.005 kg.
		3	Dimethyl Carbonate	0.500 kg.
		4	Ammonium Chloride	0.015 kg.
		5	Ammonia Gas	0.250 kg.
		6	Toluene	0.300 kg.
		7	Methanol	0.700 kg.
		8	Activated carbom	0.005 kg.

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

Case No.	81 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	ANNORA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006180AM24
RA File Number	09AX04000953 AM23
Licence No and Date	0911005908/11/10/2023

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/Apr/202324/1 dated 28/04/2023** against advance authorization **No. 0911004105 dated 13/12/2022**, 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.
SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 100 mg /Packet (SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 100 mg /Packet)	1 Number	1	SAPROPTERIN DIHYDROCHLORIDE	102.00 mg.
SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 500 mg/Packet (SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 500 mg/Packet)	1 Number	2	SAPROPTERIN DIHYDROCHLORIDE	510.00 mg.

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

Case No.	82 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	BULI CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006193AM24
RA File Number	03AX04003098 AM24
Licence No and Date	0311027841/12/10/2023

Norms Committee Decision:

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

- 1. The percentage of Hexane in export item.**
- 2. To give complete chemistry of reactant and product indicating molecular weight of each chemical and yield of the reaction.**
- 3. The value of by-product, if any, with evidence.**
- 4. Stoichiometric Material balance of the reaction.**

Case No.	83 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024

HQ File Number	HQRNORM APPLY 00006214AM24
RA File Number	03AX04003139 AM24
Licence No and Date	0311027854/12/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	84 / NC/3/MEET/Jan/202324/21																
Case Status	Case Approved																
Party Name	TADIMETY AROMATICS PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024																
HQ File Number	HQRNORM APPLY 00006217AM24																
RA File Number	07AX04001062 AM24																
Licence No and Date	0711009454/12/10/2023																
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="2">PHENYL ETHYL ISO BUTYRATE (2-phenylethyl 2-methylpropanoate – CAS No.103-48-0)</td><td rowspan="2">1 kg.</td><td>1</td><td>PHENYL ETHYL ALCOHOL</td><td>0.66 kg.</td></tr><tr><td>2</td><td>ISO BUTYRIC ACID</td><td>0.52 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PHENYL ETHYL ISO BUTYRATE (2-phenylethyl 2-methylpropanoate – CAS No.103-48-0)	1 kg.	1	PHENYL ETHYL ALCOHOL	0.66 kg.	2	ISO BUTYRIC ACID	0.52 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
PHENYL ETHYL ISO BUTYRATE (2-phenylethyl 2-methylpropanoate – CAS No.103-48-0)	1 kg.	1	PHENYL ETHYL ALCOHOL	0.66 kg.													
		2	ISO BUTYRIC ACID	0.52 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	85 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	AROHEMA INGREDIENTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006224AM24
RA File Number	26AX04000053 AM24
Licence No and Date	2611001171/13/10/2023
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/Jul/202324/9 dated 28/07/2023 against advance authorization	

No.2611000615 dated 13/06/2022, 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.
AMBRETTOLIDE VEG	1 kg.	1	7-OCTENAL	1.999 kg.
		2	INHERENT UC 12 ME	2.69 kg.
		3	ULTRACAT?	0.000089 kg.
		4	SNATCHCAT	0.000104 kg.
		5	GREEN CAT	Not imported

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

Case No.	86 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	AARTI INDUSTRIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006252AM24
RA File Number	03AX04003081 AM24
Licence No and Date	0311027889/14/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	87 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006279AM24
RA File Number	05AX04002118 AM24
Licence No and Date	0511021548/16/10/2023
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/Nov/202324/16 dated 17/11/2023** against advance authorization **No. 0511013171 dated 13/06/2022**, 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.
Tobramycin Inhalation Solution, 300mg/ 5ml(Having net content of 98.82 kg of Bulk drug (filling volume 5.4ml in each number))	1 Number	1	TOBRAMYCIN USP	306 mg.

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

Case No.	88 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006316AM24
RA File Number	09AX04000661 AM24
Licence No and Date	0911006014/17/10/2023

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/Apr/202324/1 dated 28/04/2023** against advance authorization **No. 0311020485 dated 04/01/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Colistimethate sodium powder for preparation of solution for inhalation 1000000 Units (Each vial contains: Colistimethate Sodium 1000000 U (corresponds to approximately 80 mg))	120,000 Numbers	1	Colistimethate Sodium	9.419 kg.

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

Case No.	89 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	RUMIT LIFE CARE
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006397AM24
RA File Number	03AX04002697 AM24
Licence No and Date	0311028091/20/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	90 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	GRANULES INDIA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00006422AM24			
RA File Number	09AX04000604 AM24			
Licence No and Date	0911005926/25/10/2023			
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/Jun/202324/8 dated 30/06/2023 against advance authorization No. 0911005029 dated 15/05/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Methocarbamol	1 kg.	1	Guaifenesin	1.050 kg.
		2	Sodium Methoxide Powder (SMO)	0.005 kg.
		3	Dimethyl Carbonate	0.500 kg.
		4	Ammonium Chloride	0.015 kg.
		5	Ammonia Gas	0.250 kg.
		6	Toluene	0.300 kg.

		7	Methanol	0.700 kg.
		8	Activated carbom	0.005 kg.

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

Case No.	91 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006564AM24
RA File Number	09AX04000635 AM24
Licence No and Date	0911006117/31/10/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Get the license amended to show content of API in the export product as per DML.	

Case No.	92 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	TITAN LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00006584AM24			
RA File Number	03AX04003489 AM24			
Licence No and Date	0311028387/01/11/2023			
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.
IRBESARTAN DC GRANULES 50 % ((Net Content : 2224.52 Kgs))	1 kg.	1	IRBESARTAN	0.505 kg.

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

Case No.	93 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00006707AM24
RA File Number	05AX04002383 AM24
Licence No and Date	0511021940/07/11/2023

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.
Atropine Sulfate Ophthalmic Solution USP, 1% 2 ml(Having net content of 0.60 kg of Bulk drug (filling volume 2.32 ml in each number))	1 Number	1	ATROPINE SULPHATE	20.40 mg.
Atropine Sulfate Ophthalmic Solution USP, 1% 5 ml(Having net content of 2.40 kg of Bulk drug (filling volume 5.61 ml in each number))	1 Number	2	ATROPINE SULPHATE	51.00 mg.
Atropine Sulfate Ophthalmic Solution USP, 1% 15 ml(Having net content of 1.80 kg of Bulk drug (filling volume 15.91 ml in each number))	1 Number	3	ATROPINE SULPHATE	153.0 mg.

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

Case No.	94 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024

HQ File Number	HQRNORM APPLY 00006817AM24			
RA File Number	07AX04001248 AM24			
Licence No and Date	0711009682/11/11/2023			
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. 0711004347 dated 17/06/2022 , 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.
MAGNESIUM ASPARTATE (BP / DIHYDRATE Eur.Ph) / MAGNESIUM L-ASPARTATE HYDROCHLORIDE TRIHYDRATE	1 kg.	1	L-ASPARTIC ACID	1.05 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	95 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	AARTI PHARMALABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00006860AM24			
RA File Number	03AX04003645 AM24			
Licence No and Date	0311028738/16/11/2023			
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/Oct/202122/9 dated 15/10/2021 against advance authorization No. 0310838954 dated 16/10/2020 , 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.
BUDESONIDE	1 kg.	1	16 ALPHA HYDROXY PREDNISOLONE	0.972 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	96 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007101AM24
RA File Number	34AX04000494 AM24
Licence No and Date	3411004386/29/11/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. To indicate Molecular weight of each reactant and the product. 2. Yield of the reaction with justification. 3. The value of by-product, if any, with evidence. 4. Stoichiometric Material balance of the reaction.	

Case No.	97 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007141AM24
RA File Number	03AX04003919 AM24
Licence No and Date	0311029038/01/12/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	98 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007150AM24
RA File Number	03AX04003944 AM24
Licence No and Date	0311029049/01/12/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance	

authorization No. 3111001324 dated 02/05/2022, 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.
TYLODOX GOLD WSP (Pack size 1 Kgs Jar) Each gram contains:(Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg, Net Wt Tylosin Tartrate BP (Vet) 210.00 Kgs Net Wt Doxycycline Hyclate BP 420.000 Kgs)	1 Number	1	Tylosin Tartrate BP/USP /EP	0.101 kg.
		2	Doxycycline Hyclate BP/EP/USP	0.202 kg.
TYLODOX GOLD WSP (Pack size 100 Gms sachet) Each gram contains: (Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg, Net Wt Tylosin Tartrate BP (Vet) 260.50 Kgs Net Wt Doxycycline Hyclate BP 521.00 Kgs)	1 Number	3	Tylosin Tartrate BP/USP /EP	10.1 gm.
		4	Doxycycline Hyclate BP/EP/USP	20.2 gm.
NEODOX -GOLD WSP (pack Size 100 Gms Sachet) Each gram contains : (Doxycycline Hyclate BP 100 mg, Neomycin Sulfate BP 100 mg, Net Wt Doxycycline Hyclate BP 50.00 Kgs)	1 Number	5	Doxycycline Hyclate BP/EP/USP	10.1 gm.

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

Case No.	99 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	RUMIT LIFE CARE
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007188AM24
RA File Number	03AX04003955 AM24
Licence No and Date	0311029102/04/12/2023

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.
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Betamethasone Dipropionate IP/BP/EP/USP	1 kg.	1	Betamethasone IP/BP/EP/USP	0.868 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	100 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	PIRAMAL PHARMA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00007214AM24			
RA File Number	03AX04003979 AM24			
Licence No and Date	0311029131/05/12/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Sep/202223/14 dated 27/09/2023 against advance authorization No. 0311026076 dated 07/08/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
HEXAFLUOROISOPROPYL METHYLETHER(HFMOP)	1 kg.	1	HEXA FLUOROISOPROPANOL	0.970 kg.

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

Case No.	101 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007306AM24
RA File Number	09AX04000802 AM24
Licence No and Date	0911006353/11/12/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Aug/202223/6 dated 09/09/2022 against advance authorization No.2611000439 dated 28/01/2022 , 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.
RIFAXIMIN (Ph. Eur)	1 kg.	1	4-O-Carboxymethyl-1-Deoxy-1,4-Dihydro-4-Hydroxy-1-Oxorifamycin-γ-Lactone ((Rifamycin-O)	1.50 kg.

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

Case No.	102 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007347AM24
RA File Number	05AX04002833 AM24
Licence No and Date	0511022620/12/12/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	103 / NC/3/MEET/Jan/202324/21			
Case Status	Case Approved			
Party Name	KLJ PLASTICIZERS LIMITED.			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024			
HQ File Number	HQRNORM APPLY 00007391AM24			
RA File Number	05AX04002880 AM24			
Licence No and Date	0511022658/13/12/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Dec/202324/17 dated 20/12/2023 against advance authorization No.0511022658 dated 13/12/2023 , 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.
DI-ISO DECYL ADIPATE (DIDA)(DI-ISO	1 kg.	1	ADIPIC ACID	0.35 kg.

DECYL ADIPATE (DIDA) (PACKED IN 477 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES (4,054.500 KGS. WITHOUT WASTAGE)) (EACH DRUM SHALL WEIGHT 8.5 KG AND STORAGE CAPACITY 210.000 KGS.))	2	ISO DECANOL	0.768 kg.
	3	HDPE GRANULES (TOTAL WEIGHT = 4,257.225 KGS.)	Relevant, as per packing policy

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

Case No.	104 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007395AM24
RA File Number	03AX04004138 AM24
Licence No and Date	0311029329/14/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Sep/202324/14 dated 27/09/2023** against advance authorization **No.0311026365 dated 16/08/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Atorvastatin Calcium Tablets USP 10mg((Net Content of Import Sr. No. 1 is 308.205 kgs, Sr. No. 2 is 1743.606 kg, Sr.No. 3 is 487.323 kg, Sr. No. 4 is 303000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 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.
Atorvastatin Calcium Tablets USP 20 mg ((Net Content of Import Sr. No. 1	1 Number Tablet	5	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg.

is 205.470 kgs, Sr. No. 2 is 1164.843 kg, Sr. No. 3 is 324.810 kg, Sr. No. 4 is 101000 Nos.))		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
Atorvastatin Calcium Tablets USP 40mg ((Net Content of Import Sr. No. 1 is 3857.337 kgs, Sr. No. 2 is 21833.568 kg, Sr. No. 3 is 6088.070 kg, Sr. No. 4 is 949400 Nos.))	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
Atorvastatin Calcium Tablets USP 80mg ((Net Content of Import Sr. No. 1 is 4104.000 kgs, Sr. No. 2 is 23319.720 kg, Sr. No. 3 is 6521.805 kg, Sr. No. 4 is 505000 Nos.))	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.

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

- i. **Export Product being Patented Medicine, be filed with USFDA as an NDA (New Drug Application)**
- ii. **Export to USA and Europe only.**
- iii. **Firm holding Certificate of Manufacturing Exclusivity.**

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

Case No.	105 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred

Party Name	ANNORA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007438AM24
RA File Number	09AX04000806 AM24
Licence No and Date	0911006354/18/12/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	106 / NC/3/MEET/Jan/202324/21										
Case Status	Case Approved										
Party Name	JODAS EXPOIM PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024										
HQ File Number	HQRNORM APPLY 00007758AM24										
RA File Number	09AX04000803 AM24										
Licence No and Date	0911006488/04/01/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jul/202324/9 dated 28/07/2023 against advance authorization No.0911001659 dated 30/09/2021 , 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>Heparin sodium Solution for intravenous and subcutaneous administration 5000 IU / ml - (25000 IU/ 5 ml)</td><td>1 Number</td><td>1</td><td>Heparin Sodium</td><td>137.50 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Heparin sodium Solution for intravenous and subcutaneous administration 5000 IU / ml - (25000 IU/ 5 ml)	1 Number	1	Heparin Sodium	137.50 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Heparin sodium Solution for intravenous and subcutaneous administration 5000 IU / ml - (25000 IU/ 5 ml)	1 Number	1	Heparin Sodium	137.50 mg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	107 / NC/3/MEET/Jan/202324/21
Case Status	Case Deferred
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007813AM24
RA File Number	03AX04004498 AM24
Licence No and Date	0311029998/08/01/2024

Norms Committee Decision:

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

Commercial value of 30% Isomerized Bromo Compounds obtained during manufacturing.

Case No.	108 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007842AM24
RA File Number	09AX04000903 AM24
Licence No and Date	0911006536/09/01/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Aug/202223/6 dated 09/09/2022** against advance authorization **No.2611000439 dated 28/01/2022**, 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.
RIFAXIMIN (Ph. Eur)	1 kg.	1	4-O-Carboxymethyl-1-Deoxy-1,4-Dihydro-4-Hydroxy-1-Oxorifamycin-γ-Lactone ((Rifamycin-O)	1.50 kg.

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

Case No.	109 / NC/3/MEET/Jan/202324/21
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202324/ 21 and 24/01/2024
HQ File Number	HQRNORM APPLY 00007955AM24
RA File Number	03AX04004423 AM24
Licence No and Date	0311030155/13/01/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export

product/import product in meeting **No. NC/3/MEET/Sep/202324/3 dated 27/09/2023** against advance authorization **No.0311025822 dated 28/07/2023**, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Bempedoic Acid and Ezetimibe Fixed Dose Combination Tablets ((Each Tablet content Bempedoic Acid 180mg and Ezetimibe 10mg) (Net content of Bempedoic Acid 11700.000 kgs and Ezetimibe 650.000 kgs in total Export Qty) (AA for Free of cost material as per Para 4.11 of HBP & Para 4.19 of FTP))	1 Number	1	Bempedoic Acid	189.90 mg.
		2	Ezetimibe	10.55 mg.

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

- 1. Export Product being Patented Medicine, be filed with USFDA as an NDA (New Drug Application)**
- 2. Export to USA and Europe only.**
- 3. Firm holding Certificate of Manufacturing Exclusivity.**

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