



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Nov/202324/16

DATED: 17/11/2023

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/Nov/202324/16 dated 17/11/2023 of Norms Committee - III for the year 2023-24 was held on 17/11/2023 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	T SONGZALIAN,Deputy DGFT	DGFT(HQ)
2	UTTAM SARKAR,Assistant Section Officer	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/Nov/202324/16
Case Status	Case Deferred
Party Name	INNOVASSYNTH TECHNOLOGIES (INDIA) LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00004451AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. To indicate name of reactants and products in the chemical reaction. 2. Certificate of Analysis (CoA) report of import and export of the items. 3. Complete justification for the low yield of the reaction (at each stage), indicating the impurities/isomers/precipitation formed during the reaction. 4. Production/Consumption data duly endorsed by GST.	

Case No.	2 / NC/3/MEET/Nov/202324/16
Case Status	Case Rejected
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00004198AM24
RA File Number	092404000579 AM12
Licence No and Date	0910051360/21/02/2012
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm had neither attended the Personal Hearing nor intimated to committee. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	3 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	MYLAN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00003162AM23
RA File Number	092404000288 AM13
Licence No and Date	0910053905/26/09/2012

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms 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.
SAXAGLIPTIN HYDROCHLORIDE	1 kg.	1	(S)-N-Boc -3 -Hydroxyadmantyl-D-glycine (or) KSM- I.	2.64 kg.
		2	[1S-(1alpha,3alpha,5alpha)]-3-(aminocarbonyl)-2-azabicyclo[3,1,0]hexane-2-carboxylic acid ,1,1-dimethylethylester	1.80 kg.
		3	Isopropyl alcohol	8.37 kg.
		4	n- Heptane	1.00 kg.
		5	Dry Tetrahydrofuron	2.93 kg.
		6	Methane sulfonyl chloride	1.186 kg.
		7	Triethyl amine	3.492 kg.
		8	Cyclohexane	Not required
		9	Tetramethyl ethylene diamine	1.741 kg.
		10	Methanol	2.98 kg.
		11	Pottsium Carbonate	2.318 kg.
		12	Dichloromethane	17.08 kg.
		13	Methane Sulfonic Acid	1.486 kg.

Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms.

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

Case No.	4 / NC/3/MEET/Nov/202324/16
Case Status	Case Rejected
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00003010AM24
RA File Number	092404000374 AM15
Licence No and Date	0910061119/17/10/2014
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm had neither attended the Personal Hearing nor intimated to committee. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	5 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00004184AM23
RA File Number	522404000042 AM17
Licence No and Date	5210042032/30/09/2016
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 provide technical justification indicating material balance on molar basis. 2. Yield of the reaction.	

Case No.	6 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00002204AM23
RA File Number	052304000048 AM20
Licence No and Date	0510410475/03/05/2019
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and it was decided to call for following information/documents from the firm:-	

No justification for enhancement in view of import item description and approved composition in DML.

Case No.	7 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	NOVEL NUTRIENTSS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00001063AM24
RA File Number	072404000056 AM20
Licence No and Date	0710115041/11/06/2019
Norms Committee Decision: The committee considered the case as per agenda and it was observed that the firm vide email dated 03/11/2023 has informed that they have surrendered the license. Therefore, the committee decided to withdraw the application of the firm.	

Case No.	8 / NC/3/MEET/Nov/202324/16													
Case Status	Case Approved													
Party Name	YASHO INDUSTRIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023													
HQ File Number	HQRNORM REVIW00006311AM23													
RA File Number	039504000760 AM20													
Licence No and Date	0310832692/11/11/2019													
Norms Committee Decision:														
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td rowspan="2">YAPOX CL 30/10" HYDROQUINONE BIS" (1 kg. 2 HYDROXY ETHYL ETHER)</td><td rowspan="2"></td><td>1</td><td>HYDROQUINONE</td><td>0.735 kg.</td></tr><tr><td>2</td><td>ETHYLENE CARBONATE</td><td>1.232 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	YAPOX CL 30/10" HYDROQUINONE BIS" (1 kg. 2 HYDROXY ETHYL ETHER)		1	HYDROQUINONE	0.735 kg.	2	ETHYLENE CARBONATE	1.232 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
YAPOX CL 30/10" HYDROQUINONE BIS" (1 kg. 2 HYDROXY ETHYL ETHER)		1	HYDROQUINONE	0.735 kg.										
		2	ETHYLENE CARBONATE	1.232 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	9 / NC/3/MEET/Nov/202324/16
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Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00000303AM24
RA File Number	039404000888 AM20
Licence No and Date	0310834332/20/01/2020

Norms Committee Decision:

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

- Against 100 kg of export obligation of 'URSODEOXYCHOLIOIC ACID (UDCA)', the export of 85 kg of "3a-Hydroxy-7-keto-5b-cholan-24-oic acid (IP-5)" may be endorsed based on the main raw material Cholic Acid.
- Import of input item No. 4 and 6 are not allowed for export of "3a-Hydroxy-7-keto-5b-cholan-24-oic acid (IP-5)". Custom duty plus interest etc. will be paid for such import, as per policy.
- For any excess of other inputs imported in each license, the firm will pay custom duty + interest as applicable under the Policy.

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
3a-Hydroxy-7- keto-5b-cholan-24-oic acid (IP-5) [7-Ketolithocholic acid (3a-Hydroxy- 7-oxo-5β-cholanic acid), Minimum 99.75%. No single related or unrelated impurity should be more than 0.05%]	1 kg.	1	CHOLIC ACID	1. 65kg
		2	HYDRAZINE HYDRATE (80% SOLUTION)	1.65 kg
		3	IEP OX 239 SPRAY DRIED ENZYME POWDER	0.033 kg
		4	IEP OX 235 SPRAY DRIED ENZYME POWDER	Not required
		5	IEP OX 152 SPRAY DRIED ENZYME POWDER	0.050 kg
		6	IEP SP 41 SPRAY DRIED ENZYME POWDER	Not required

		7	IEP OX 243 SPRAY DRIED ENZYME POWDER	0.040 kg
		8	(B-NAD)B-NICOTINAMIDE-ADENINE DINUCLEOTIDE (COENZYME-1)	0.008 kg

Note: Above norms are for regularization and closure purpose only. No fresh license will be issued on above said ad-hoc norms.

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

Case No.	10 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	AURA LIFECARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00001012AM24
RA File Number	342404000323 AM20
Licence No and Date	3410045804/23/01/2020
Norms Committee Decision:	
The committee considered the request of firm for review of ad-hoc norms and it was decided that RA may work-out the import entitlement of Dextrose in line with SION A-325 on pro-rata basis or as applied whichever is lower.	

Case No.	11 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	NOVEL NUTRIENTSS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00001058AM24
RA File Number	072404000038 AM21
Licence No and Date	0710116503/26/05/2020
Norms Committee Decision:	
The committee considered the case as per agenda and it was observed that the firm vide email stated that they surrender the above licence. Hence , the committee decided to withdraw the case.	

Case No.	12 / NC/3/MEET/Nov/202324/16
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Case Status	Case Approved																
Party Name	CLARIANT INDIA LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023																
HQ File Number	018205001343AM21																
RA File Number	039404000110 AM21																
Licence No and Date	0310836469/01/06/2020																
Norms Committee Decision:																	
Ms. Meghana Abhijit Karpe, Logistic Head and Shri Prashant Wadaskar, Plant Manager of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is lower: -																	
<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">PIROCTONE OLAMINE OR VIPIROX (Octopirox plus)</td><td rowspan="3">1 kg.</td><td>1</td><td>Dimethyl acrylic acid ester</td><td>0.84 kg.</td></tr><tr><td>2</td><td>Hydroxyl amine hydrochloride</td><td>1.54 kg.</td></tr><tr><td>3</td><td>Isononyl acid chloride</td><td>1.667 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PIROCTONE OLAMINE OR VIPIROX (Octopirox plus)	1 kg.	1	Dimethyl acrylic acid ester	0.84 kg.	2	Hydroxyl amine hydrochloride	1.54 kg.	3	Isononyl acid chloride	1.667 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
PIROCTONE OLAMINE OR VIPIROX (Octopirox plus)	1 kg.	1	Dimethyl acrylic acid ester	0.84 kg.													
		2	Hydroxyl amine hydrochloride	1.54 kg.													
		3	Isononyl acid chloride	1.667 kg.													
RA concerned may take further necessary action as per above decision of NC																	

Case No.	13 / NC/3/MEET/Nov/202324/16								
Case Status	Case Approved								
Party Name	BROOKS LABORATORIES LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023								
HQ File Number	HQRNORM REVIW00004249AM24								
RA File Number	302404000010 AM21								
Licence No and Date	3010105213/02/06/2020								
Norms Committee Decision:									
The Committee considered the request of firm for fixation of ad-hoc norms 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></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					

Meropenem Injection USP1000 mg.Each vial contains Sterile Meropenem Trihydrate USP equ to Anhydrous Meropenem1000mg (SterileSodium Carbonate USP equ to Sodium 90.2mg with Pre-Import condition in terms of Para 4.13(iii) of FTP 2015-20 import should be made 1st &EO shall be fulfilled within 12 months from the dt. of import of each consignment in terms of Appdix-4J)	1 Number	1	MEROPENEM WITH SODIUM CARBONATE USP	1.29 gm.
Export Item Name: Meropenem Injection 500 mg USPEach vial contains Sterile Meropenem Trihydrate USP equ to Anhydrous Meropenem 500mg (SterileSodium Carbonate USP equ to Sodium 90.2mg with Pre-Import condition in terms of Para 4.13(iii) of FTP 2015-20 import shud be made 1st &EO shall be fulfilled within 12 months from the dt. of import of each consignment in terms of Appdix-4J)	1 Number	2	MEROPENEM WITH SODIUM CARBONATE USP	0.645 gm.

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

Case No.	14 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	AURA LIFECARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00001123AM24
RA File Number	342404000133 AM21
Licence No and Date	3410046298/18/08/2020
Norms Committee Decision:	
The committee considered the request of firm for review of ad-hoc norms and it was decided that RA may work-out the import entitlement of Dextrose in line with SION A-325 on pro-rata basis or as applied whichever is lower.	

Case No.	15 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00005055AM23
RA File Number	092404000282 AM21

Licence No and Date	0910069242/22/09/2020			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under.				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tobramycin for Inhalation solution 60 mg / ml (300 mg / 5 ml) Net quantity of export product 35.04 Kgs(Each mL contains Tobramycin sulfate equivalent to Tobramycin-60mg. Excipients q.s.)	1 Number	1	Tobramycin Sulfate	466.49 mg.
Tobramycin for Inhalation solution 75 mg / ml (300 mg / 4 ml) Net quantity of export product 23.36 Kgs(Each mL contains Tobramycin sulfate equivalent to Tobramycin-75mg. Excipients q.s.)	1 Number	2	Tobramycin Sulfate	466.49 mg.

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

Case No.	16 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00004153AM23
RA File Number	039404000571 AM21
Licence No and Date	0310839148/27/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant information / documents.	

Case No.	17 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	018205001869AM21
RA File Number	052404000441 AM21

Licence No and Date	0510415972/24/11/2020
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:- - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity. - Sample of shipping bills and bill of entry of the export products along with statement of Input-output as per export documents of the said authorization.	

Case No.	18 / NC/3/MEET/Nov/202324/16																				
Case Status	Case Approved																				
Party Name	REFLUX PHARMACEUTICALS PRIVATE LIMITED																				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023																				
HQ File Number	HQRNORM APPLY 00001513AM24																				
RA File Number	NA																				
Licence No and Date	0311001445/03/02/2021																				
Norms Committee Decision:																					
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																					
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td rowspan="3">TOLFENAMIC ACID</td><td rowspan="3">1 kg.</td><td>1</td><td>3 CHLORO 2 METHYLANILINE 99 PERCENT MIN</td><td>0.67 kg.</td></tr><tr><td>2</td><td>ORTHO CHLORO BENZOIC ACID 99 PERCENT MIN</td><td>0.75 kg.</td></tr><tr><td>3</td><td>DIMETHYL FORMAMIDE 99 POINT 9 PERCENT</td><td>2.13 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	TOLFENAMIC ACID	1 kg.	1	3 CHLORO 2 METHYLANILINE 99 PERCENT MIN	0.67 kg.	2	ORTHO CHLORO BENZOIC ACID 99 PERCENT MIN	0.75 kg.	3	DIMETHYL FORMAMIDE 99 POINT 9 PERCENT	2.13 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																	
TOLFENAMIC ACID	1 kg.	1	3 CHLORO 2 METHYLANILINE 99 PERCENT MIN	0.67 kg.																	
		2	ORTHO CHLORO BENZOIC ACID 99 PERCENT MIN	0.75 kg.																	
		3	DIMETHYL FORMAMIDE 99 POINT 9 PERCENT	2.13 kg.																	
RA concerned may take further necessary action as per above decision of NC.																					

Case No.	19 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00004407AM24
RA File Number	03AA04023340 AM21
Licence No and Date	0311001698/16/02/2021
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. Copy of Bill of Entry of import item. 2. CoA of import item from foreign supplier.	

Case No.	20 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00101696AM21
RA File Number	09AA04005325 AM21
Licence No and Date	0911000494/11/03/2021
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. Drug Manufacturing Licence (DML) with approved composition. 2. Master Batch Formula.	

Case No.	21 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	BROOKS LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00004240AM24
RA File Number	30AA04005114 AM21
Licence No and Date	3011000438/25/03/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP	

Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Meropenem Injection USP 1000 mg each v	1 Number	1	MEROPENEM WITH SODIUM CAARBONATE USP	1.29 gm

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

Case No.	22 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	CLARIANT INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00004498AM24
RA File Number	03AA04009823 AM22
Licence No and Date	0311003530/04/05/2021

Norms Committee Decision:

Ms. Meghana Abhijit Karpe, Logistic Head and Shri Prashant Wadaskar, Plant Manager of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PIROCTONE OLAMINE OR VIPIROX (Octopirox plus)	1 kg.	1	Dimethyl acrylic acid ester	0.84 kg.
		2	Hydroxyl amine hydrochloride	1.54 kg.
		3	Isononyl acid chloride	1.667 kg.

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

Case No.	23 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM REVIW00004760AM24			
RA File Number	03AA04021964 AM22			
Licence No and Date	0311004323/04/06/2021			
Norms Committee Decision:				
The Committee considered the request of firm for fixation of ad-hoc norms 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.
Bleomycin For Injection USP 15 Units (Lyophilised)(Bleomycin For Injection USP 15 Units (Lyophilised) (Net Content of Bleomycin Sulfate, Non Sterile - 115 Grams (10 mg in each vial))	1 Number	1	Bleomycin Sulfate, Non Sterile	10 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	24 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00003403AM23
RA File Number	08AA04007143 AM22
Licence No and Date	0811001742/15/06/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	25 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00138116AM22
RA File Number	26AA04002063 AM22
Licence No and Date	2611000198/13/07/2021

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. **Complete and balanced chemical reactions for each step, as given in process details, alongwith molar weight and percentage yield on molar basis.**
2. **Justification for molar excess shown for various inputs.**
3. **End-use of intermediate.**

Case No.	26 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	DIAMINES AND CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00145203AM22
RA File Number	34AA04005573 AM22
Licence No and Date	3411000885/22/07/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PIPERAZINE ANHYDROUS	1 kg.	1	PIPERAZINE CRUDE OR PIPERAZINE MIXTURE (Percentage purity not more than 48.1%)	2.047 kg.

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

Case No.	27 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	SYNOKEM PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00147457AM22
RA File Number	05AA04059070 AM22
Licence No and Date	0511003826/26/07/2021

Norms Committee Decision:

Shri Krishan Khemka, Consultant and Shri Deepak Nagar, Manager of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has advised to the firm to amend the license from concerned RA with correct export product and import item.

Case No.	28 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	SUNDYOTA NUMANDIS PROBIOCEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00004161AM24
RA File Number	08AA04021121 AM22
Licence No and Date	0811002324/16/08/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	29 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00164102AM22
RA File Number	03AA04065031 AM22
Licence No and Date	0311006216/17/08/2021
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 information / documents.	

Case No.	30 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00005936AM23
RA File Number	34AA04006527 AM22
Licence No and Date	3411000984/17/08/2021
Norms Committee Decision:	
Decision: Dr. Dhaval Patel, Technical Expert, Shri Dhruval Parmar (Exim) of the firm had attended the Personal	

Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Limbunile(3,7-Dimethyl-2(3), 6-nonadienonitrile))	1 kg.	1	Ethyl Heptenone	1.145 kg.
		2	Cyano Acetic acid (70%)	1.75 kg.

Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms.

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

Case No.	31 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00006174AM23
RA File Number	NA
Licence No and Date	3411000984/17/08/2021

Norms Committee Decision:

Decision: Dr. Dhaval Patel, Technical Expert, Shri Dhruval Parmar (Exim) of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Limbunile(3,7-Dimethyl-2(3), 6-nonadienonitrile))	1 kg.	1	Ethyl Heptenone	1.145 kg.
		2	Cyano Acetic acid (70%)	1.75 kg.

Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms.

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

Case No.	32 / NC/3/MEET/Nov/202324/16
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Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00170502AM22
RA File Number	08AA04022482 AM22
Licence No and Date	0811002393/25/08/2021

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/202324/15 dated 13/10/2023** against advance authorization **No.0811002958 dated 22/10/2021** , 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.
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 1ML VIAL(EACH ML CONTAINS: VINORELBINE TARTRATE PH.EUR EQ. TO VINORELBINE 10 MG)	1 Number	1	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR (Water content 2.3%)	14.33 mg.
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 5ML VIAL(EACH ML CONTAINS: VINORELBINE TARTRATE PH.EUR EQ. TO VINORELBINE 10 MG [IN WHICH ACTIVE INGREDIENT VINORELBINE TARTRATE USED IS 183.000 GRAMS])	1 Number	2	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR (Water content 2.3%)	71.66 mg.

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

Case No.	33 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	DIAMINES AND CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00184161AM22
RA File Number	34AA04007354 AM22
Licence No and Date	3411001111/15/09/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PIPERAZINE ANHYDROUS	1 kg.	1	PIPERAZINE CRUDE OR PIPERAZINE MIXTURE (Percentage purity not more than 48.1%)	2.047 kg.

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

Case No.	34 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	CUCKOS PHARMACEUTICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00184568AM22
RA File Number	33AA04006480 AM22
Licence No and Date	3311000430/15/09/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	35 / NC/3/MEET/Nov/202324/16				
Case Status	Case Approved				
Party Name	ASOJ SOFT CAPS PVT LTD				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023				
HQ File Number	HQRNORM APPLY 00190578AM22				
RA File Number	34AA04007816 AM22				
Licence No and Date	3411001148/22/09/2021				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.

NERVERON (each capsule containing 200 mg of Alpha Lipoic Acid)	1 Number	1	ALPHA LIPOIC ACID	204.00 mg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	36 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00195372AM22
RA File Number	34AA04006808 AM22
Licence No and Date	3411001180/27/09/2021

Norms Committee Decision:

Dr. Dhaval Patel, Technical Expert, Shri Dhruval Parmar (Exim) of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -

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

Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms.

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

Case No.	37 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00212058AM22

RA File Number	03AA040109332 AM22
Licence No and Date	0311007711/14/10/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	38 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00226905AM22
RA File Number	05AA04094141 AM22
Licence No and Date	0511005704/26/10/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	39 / NC/3/MEET/Nov/202324/16															
Case Status	Case Approved															
Party Name	BHARAT PARENTERALS LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023															
HQ File Number	HQRNORM APPLY 00239596AM22															
RA File Number	34AA04008748 AM22															
Licence No and Date	3411001363/02/11/2021															
Norms Committee Decision:																
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>CEFACLOX CAPSULES USP 500MG((EACH HARD GELATIN CAPSULE CONTAIN CEFACLOX USP EQ TO ANHYDROUS CEFACLOX 500MG) (TOTAL CONTENT: CEFACLOX IP/BP/USP 85.1256 KGS)151200 Capsules)</td><td>1 Number</td><td>1</td><td>CEFACLOX (Average water content 4.3%)</td><td>531.93 mg</td></tr><tr><td>CEFACLOX EXTENDED-RELEASE TABLETS USP 750 MG((EACH FILM COATED EXTENDED RELEASE TABLET CONTAINS</td><td>1 Number</td><td>2</td><td>CEFACLOX (Average water content 4.3%)</td><td>797.90 mg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CEFACLOX CAPSULES USP 500MG((EACH HARD GELATIN CAPSULE CONTAIN CEFACLOX USP EQ TO ANHYDROUS CEFACLOX 500MG) (TOTAL CONTENT: CEFACLOX IP/BP/USP 85.1256 KGS)151200 Capsules)	1 Number	1	CEFACLOX (Average water content 4.3%)	531.93 mg	CEFACLOX EXTENDED-RELEASE TABLETS USP 750 MG((EACH FILM COATED EXTENDED RELEASE TABLET CONTAINS	1 Number	2	CEFACLOX (Average water content 4.3%)	797.90 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
CEFACLOX CAPSULES USP 500MG((EACH HARD GELATIN CAPSULE CONTAIN CEFACLOX USP EQ TO ANHYDROUS CEFACLOX 500MG) (TOTAL CONTENT: CEFACLOX IP/BP/USP 85.1256 KGS)151200 Capsules)	1 Number	1	CEFACLOX (Average water content 4.3%)	531.93 mg												
CEFACLOX EXTENDED-RELEASE TABLETS USP 750 MG((EACH FILM COATED EXTENDED RELEASE TABLET CONTAINS	1 Number	2	CEFACLOX (Average water content 4.3%)	797.90 mg												

CEFACLOL USP EQ TO ANHYDROUS CEFACLOL 750MG)(TOTAL CONTENT: CEFACLOL IP/BP/USP 85.176 KGS) 100800 Tabletss)				
CEFACLOL FOR ORAL SUSPENSION USP 125 MG /5ML IN 75ML BOTTLE((EACH 5ML OF RECONSTITUTED SUSPENSION CONTAINS CEFACLOL USP EQ TO ANHYDROUS CEFACLOL 125 MG)(TOTAL CONTENT:CEFACLOL IP/BP/USP 31.65 KGS)15000 Bottles)	1 Number	3	CEFACLOL (Average water content 4.3%)	2053.40 mg
CEFACLOL FOR ORAL SUSPENSION USP 250 MG /5ML IN 75ML BOTTLE((EACH 5ML OF RECONSTITUTED SUSPENSION CONTAINS CEFACLOL USP EQ TO ANHYDROUS CEFACLOL 250 MG)(TOTAL CONTENT:CEFACLOL IP/BP/USP 46.431 KGS)11000 Bottles)	1 Number	4	CEFACLOL (Average water content 4.3%)	4106.80 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	40 / NC/3/MEET/Nov/202324/16
Case Status	Case Rejected
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00261092AM22
RA File Number	09AA04016734 AM22
Licence No and Date	0911001888/22/11/2021
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm had neither attended the Personal Hearing nor intimated to committee. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	41 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	LAZERHEAD LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00266328AM22
RA File Number	09AA04012424 AM22

Licence No and Date	0911001950/26/11/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	42 / NC/3/MEET/Nov/202324/16																			
Case Status	Case Approved																			
Party Name	YASHO INDUSTRIES LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023																			
HQ File Number	HQRNORM APPLY 00272724AM22																			
RA File Number	03AA040127775 AM22																			
Licence No and Date	0311009114/02/12/2021																			
Norms Committee Decision:																				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Oct/202324/15 dated 13/10/2023 against advance authorization No.0311008170 dated 02/11/2021 , 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:-																				
<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">2,5-DIMERCAPTO-1,3,4-THIADIAZOLE (YALUB DMTD)</td><td rowspan="3">1 kg.</td><td>1</td><td>HYDRAZINE HYDRATE (Min. 80% purity)</td><td>0.4125 kg.</td></tr><tr><td>2</td><td>CAUSTIC SODA</td><td>0.266 kg.</td></tr><tr><td>3</td><td>CARBON DISULPHIDE</td><td>0.048 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	2,5-DIMERCAPTO-1,3,4-THIADIAZOLE (YALUB DMTD)	1 kg.	1	HYDRAZINE HYDRATE (Min. 80% purity)	0.4125 kg.	2	CAUSTIC SODA	0.266 kg.	3	CARBON DISULPHIDE	0.048 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
2,5-DIMERCAPTO-1,3,4-THIADIAZOLE (YALUB DMTD)	1 kg.	1	HYDRAZINE HYDRATE (Min. 80% purity)	0.4125 kg.																
		2	CAUSTIC SODA	0.266 kg.																
		3	CARBON DISULPHIDE	0.048 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	43 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM REVIW00004710AM24			
RA File Number	03AA040124486 AM22			
Licence No and Date	0311009090/02/12/2021			

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms 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.
DIISOPROPYL ETHER (Purity more than 99.21%) (Moisture less than 1000 PPM)	1 kg.	1	CRUDE DIISOPROPYL ETHER (Purity not more than 95%)	1.25 kg.

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

Case No.	44 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00277912AM22
RA File Number	05AA040108247 AM22
Licence No and Date	0511006681/07/12/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CEFEPIME POWDER FOR SOLUTION FOR INJECTION, WEIGHT 1 GMS/VIAL (CEFEPIME HCL+L- ARGININE STERILE USP)	1 Number	1	CEFEPIME HCL+L- ARGININE STERILE USP	1.05 gm.
CEFEPIME POWDER FOR SOLUTION FOR INJECTION, WEIGHT 2 GMS/VIAL (CEFEPIME HCL+L- ARGININE STERILE USP)	1 Number	2	CEFEPIME HCL+L- ARGININE STERILE USP	2.10 gm.

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

Case No.	45 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00289566AM22
RA File Number	34AX04000036 AM22
Licence No and Date	3411001553/17/12/2021

Norms Committee Decision:

Dr. Dhaval Patel, Technical Expert, Shri Dhruval Parmar (Exim) of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PHENOXYETHYL ISOBUTYRATE (((Phenoxy) ethyl 2-methylpropanoate))	1 kg.	1	ISOBUTYRIC ACID	0.5633 kg.

Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms.

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

Case No.	46 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00289569AM22
RA File Number	34AX04000035 AM22
Licence No and Date	3411001554/17/12/2021

Norms Committee Decision:

Dr. Dhaval Patel, Technical Expert, Shri Dhruval Parmar (Exim) of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -

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

EM PENTANOATE (ETHYL-2-METHYL PENTANOATE)	1 kg.	1	Propionaldehyde	1.20 kg.
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Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms.

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

Case No.	47 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	NATCO PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00004488AM24
RA File Number	09AX04000043 AM22
Licence No and Date	0911002121/21/12/2021
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 information / documents.	

Case No.	48 / NC/3/MEET/Nov/202324/16													
Case Status	Case Approved													
Party Name	CLARIANT INDIA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023													
HQ File Number	HQRNORM REVIW00004497AM24													
RA File Number	03AX04000499 AM22													
Licence No and Date	0311009919/30/12/2021													
Norms Committee Decision:														
Ms. Meghana Abhijit Karpe, Logistic Head and Shri Prashant Wadaskar, Plant Manager of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is lower: -														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>PIROCTONE OLAMINE OR VIPIROX</td><td>1 kg.</td><td>1</td><td>Dimethyl acrylic acid ester</td><td>0.84 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PIROCTONE OLAMINE OR VIPIROX	1 kg.	1	Dimethyl acrylic acid ester	0.84 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
PIROCTONE OLAMINE OR VIPIROX	1 kg.	1	Dimethyl acrylic acid ester	0.84 kg.										

(Octopirox plus)		2	Hydroxyl amine hydrochloride	1.54 kg.
		3	Isononyl acid chloride	1.667 kg.

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

Case No.	49 / NC/3/MEET/Nov/202324/16																			
Case Status	Case Approved																			
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD																			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023																			
HQ File Number	HQRNORM APPLY 00324009AM22																			
RA File Number	03AX04000495 AM22																			
Licence No and Date	0311010688/19/01/2022																			
Norms Committee Decision:																				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																				
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="4">POLY 4, 4 ISOPROPYLIDENEDIPHENOL C12-C15 ALCOHOL PHOSPHITE</td><td rowspan="4">27000.0 kg.</td><td>1</td><td>PHENOL</td><td>13770.0 kg.</td></tr><tr><td>2</td><td>YELLOW PHOSPHORUS</td><td>1471.5 kg.</td></tr><tr><td>3</td><td>BISPHENOL A</td><td>5562.0 kg.</td></tr><tr><td>4</td><td>C12 C15 ALCOHOL</td><td>19710.0 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	POLY 4, 4 ISOPROPYLIDENEDIPHENOL C12-C15 ALCOHOL PHOSPHITE	27000.0 kg.	1	PHENOL	13770.0 kg.	2	YELLOW PHOSPHORUS	1471.5 kg.	3	BISPHENOL A	5562.0 kg.	4	C12 C15 ALCOHOL	19710.0 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
POLY 4, 4 ISOPROPYLIDENEDIPHENOL C12-C15 ALCOHOL PHOSPHITE	27000.0 kg.	1	PHENOL	13770.0 kg.																
		2	YELLOW PHOSPHORUS	1471.5 kg.																
		3	BISPHENOL A	5562.0 kg.																
		4	C12 C15 ALCOHOL	19710.0 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	50 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	BEST VALUE CHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM REVIW00007005AM23			
RA File Number	34AX04000212 AM22			
Licence No and Date	3411001750/04/02/2022			

Norms Committee Decision:

Decision: Dr. Dhaval Patel, Technical Expert, Shri Dhruval Parmar (Exim) of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -

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.

Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms.

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

Case No.	51 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00000257AM24
RA File Number	03AX04001590 AM22
Licence No and Date	0311013222/22/03/2022
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 information / documents.	

Case No.	52 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00401252AM22
RA File Number	03AX04001906 AM22
Licence No and Date	0311013320/25/03/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.72/NC/3/MEET/Oct/202122/9 dated 15/10/2021** against advance authorization **No. 0310837496 dated 30/07/2020**, 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:-

Sl. No.	Export Product	Qty.
1	62/0- Phytosterol Natural Refined Phytosterol 95%	120000.000 kg.
2	62/0- Natural Mixed Tocopherol 70%	55000.000 kg.

Sl. No.	Import Item	Qty.
1	Fatty Acid Distillate / Deoderised Distillate	1842500 kg.
2	Acetone	88000 kg.
3	N-HEPTANE	188100 kg.

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

Case No.	53 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	KRITI NUTRIENTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00408410AM22
RA File Number	56AX04000134 AM22
Licence No and Date	5611000874/30/03/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Soya Lecithin Liquid Food Grade (Non GMO)	1MT	1	Soya Lecithin Liquid	1.01 MT
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RA concerned may take further necessary action as per above decision of NC.

Case No.	54 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00409480AM22
RA File Number	34AX04000458 AM22
Licence No and Date	3411002061/31/03/2022
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:- Copy of Master-Batch Formula for each export item.	

Case No.	55 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	AUROBINDO PHARMA LTD			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM APPLY 00410013AM22			
RA File Number	09AX04000193 AM22			
Licence No and Date	0911002816/31/03/2022			
Norms Committee Decision:				
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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/202324/15 dated 13/10/2023 against advance authorization No. 0910066762 dated 25/10/2018 , 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.
AMOXYCILLIN AND CLAVULANATE POTASSIUM	1 Number	1	6-APA (6-Amino Penicillanic Acid)	325.00 mg.

TABLETS 625 MG. (Each film coated Tablet contains: Amoxicillin Trihydrate equivalent to Anhydrous Amoxicillin 500 mg an Clavulanate Potassium equivalent to Clavulanic Acid 125 mg.		2	D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]	281.86 mg.
		3	Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)	1.00 mg.
		4	Diluted Clavulanate Potassium (1:1) / Potassium Clavulanate Diluted with Microcrystalline Cellulose (1:1)	297.825 mg.

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

Case No.	56 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000168AM23
RA File Number	03AX04000080 AM23
Licence No and Date	0311013777/11/04/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ROSUVASTATIN CALCIUM	1 kg.	1	Tert-Butyl(E)-(6-(2-(4-(4-fluorophenyl)-6-Isopropyl-2-(Methyl(Methyl Sulfonyl) Amino Pyrimidin-5-yl)Vinyl) (4R,6S)-2,2-Dim	1.30 kg.
		2	ETHYL ACETATE	0.674 kg.
		3	METHANOL	1.874 kg.
		4	TOLUENE	0.772 kg.

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

Case No.	57 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000220AM23
RA File Number	08AX04000742 AM22
Licence No and Date	0811004640/13/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Aug/202324/11 dated 22/08/2023** against advance authorization **No.0811002528 dated 07/09/2021** , 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	1	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	61.87 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [5 ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100 MG)	1 Number Vial	2	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	618.70 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL](EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)	1 Number Vial	3	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	1237.39 mg/vial
METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL](EACH ML CONTAINS: METHOTREXATE USP 25MG)	1 Number Vial	4	METHOTREXATE EP / BP / IP / USP / PH. EUR.	306.867 mg/vial

			(Moisture and Residual Solvents content not less than 12.49 % in API)	
METHOTREXATE INJECTION BP 25MG/ML [20ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	5	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	590.57 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	6	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	1181.15 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 8.175 KGS.])	1 Number Vial	7	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	5737.00 mg/vial
RA concerned may take further necessary action as per above decision of NC				

Case No.	58 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000256AM23
RA File Number	09AX04000404 AM22
Licence No and Date	0911002859/18/04/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202223/22 dated 24/03/2022 against advance authorization No.0911003834 dated 18/10/2022, 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.
Amoxicillin and Clavulanate Potassium Tablets 1000 mg((Relevant bulk drug content in the Export product Amoxicillin trihydrate equivalent to Amoxicillin 19687.50 kg and Clavulanate Potassium equivalent to Clavulanic acid 2812.5 kg))	1 Number Tablet	1	6-Amino Penicillanic Acid (6-APA)	576.40 mg
		2	D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]	496.38 mg
		3	Potassium Clavulanate Diluted with Microcrystalline Cellulose (1:1)	302.03 mg

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

Case No.	59 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000389AM23
RA File Number	08AX04000767 AM22
Licence No and Date	0811004766/23/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Jun/202324/8** dated **30/06/2023** against advance authorization **No.0811007534 dated 10.03.2023**, 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.
NALTREXONE HYDROCHLORIDE TABLETS 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE PH. EUR. 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 114.000 KGS.])	1 Number	1	NALTREXONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR (All Alcoholic Solvents and water content NLT 1.86% as per COA of Import item).	51.93 mg/tablet

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

Case No.	60 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000438AM23
RA File Number	03AX04001990 AM22
Licence No and Date	0311014190/26/04/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ARTEMETHER	1 kg.	1	ARTEMISININ	1.04 kg.
		2	SODIUM BOROHYDRIDE	0.188 kg.
		3	TRIMETHYL ORTHO ACETATE	0.50 kg.

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

Case No.	61 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	UNITED BIOCEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000479AM23
RA File Number	05AX04000238 AM23
Licence No and Date	0511012150/28/04/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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TRIMEBUTINE MALEATE TABLETS - 200MG	1 Number	1	TRIMEBUTINE MALEATE EP	203.95 mg
TRIMEBUTINE MALEATE TABLETS - 300 MG	1 Number	2	TRIMEBUTINE MALEATE EP	305.85 mg

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

Case No.	62 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000483AM23
RA File Number	03AX04000200 AM23
Licence No and Date	0311014256/28/04/2022

Norms Committee Decision:

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

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 5 Gm Tube Tot Wt: 150 Kgs (Net Cont: Beta 0.18Kgs, Ceto 10.80Kgs, Fusi 3 Kgs, Macro 2.70 Kgs, Tubes 30000 Nos))	1 Number
2	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 15 Gm Tube Tot Wt: 2400 Kgs (Net Cont: Beta 2.91Kgs, Ceto 172.80Kgs, Fusi 48 Kgs, Macro 43.2 Kgs, Tubes 160000 Nos))	1 Number
3	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 30 Gm Tube Tot Wt: 3750 Kgs (Net Cont: Beta 4.55Kgs, Ceto 270Kgs, Fusi 75 Kgs, Macro 67.50 Kgs, Tubes 125000 Nos))	1 Number
4	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 60 Gm Tube Tot Wt: 2100 Kgs (Net Cont: Beta 2.55Kgs, Ceto 151.20Kgs, Fusi 42 Kgs, Macro 37.80 Kgs, Tubes 35000 Nos))	1 Number
5	Medical Creams & Ointments(Fusidic Acid Cream 15 Gm Tube Tot Wt: 2400 Kgs (Net Cont: Fusi 48 Kgs, Tubes 160000 Nos))	1 Number
6	Medical Creams & Ointments(Fusidic Acid Cream 30 Gm Tube Tot Wt: 3000 Kgs (Net Cont: Fusi 60 Kgs, Tubes 100000 Nos))	1 Number

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

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

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

Case No.	63 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000485AM23
RA File Number	03AX04000399 AM23
Licence No and Date	0311014263/29/04/2022
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 information / documents.	

Case No.	64 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000500AM23
RA File Number	09AX04000372 AM22
Licence No and Date	0911002924/29/04/2022
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	

- i. **Justification of low yield i.e. 72%.**
 ii. **Production/consumption data certified by GST for last one year.**

Case No.	65 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000501AM23
RA File Number	09AX04000388 AM22
Licence No and Date	0911002925/29/04/2022

Norms Committee Decision:

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

- i. **Justification of low yield i.e. 72%.**
 ii. **Production/consumption data certified by GST for last one year.**

Case No.	66 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000502AM23
RA File Number	09AX04000389 AM22
Licence No and Date	0911002926/29/04/2022

Norms Committee Decision:

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

- i. **Justification of low yield i.e. 72%.**
 ii. **Production/consumption data certified by GST for last one year.**

Case No.	67 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000506AM23

RA File Number	09AX04000079 AM23			
Licence No and Date	0911002928/29/04/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
RAMELTEON	1 Kg	1	1,2,6,7-TETRAHYDRO-8H-INDENO [5,4-B]FURAN-8-ONE	3.05 kg
		2	CHLORO ACETONITRILE	2.25 kg
		3	S-IBUPROFEN	2.47 kg

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

Case No.	68 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000512AM23
RA File Number	08AX04000074 AM23
Licence No and Date	0811004832/29/04/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	69 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000513AM23
RA File Number	08AX04000823 AM22
Licence No and Date	0811004833/29/04/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Oct/202324/15** dated **13/10/2023** against advance authorization No.**0811002958** dated **22.10.2021**, 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.
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 1ML VIAL(EACH ML CONTAINS: VINORELBINE TARTRATE PH.EUR EQ. TO VINORELBINE 10 MG)	1 Number	1	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR (Water content 2.3 %)	14.33 mg
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 5ML VIAL(EACH ML CONTAINS: VINORELBINE TARTRATE PH.EUR EQ. TO VINORELBINE 10 MG [IN WHICH ACTIVE INGREDIENT VINORELBINE TARTRATE USED IS 1568.000 GRAMS])	1 Number	2	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR (Water content 2.3 %)	71.66 mg

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

Case No.	70 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000548AM23
RA File Number	03AX04000420 AM23
Licence No and Date	0311014381/04/05/2022
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-	

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Bacitracin Zinc Ointment 0.5 OZ /14 GM Tube Tot Wt: 400.54Kgs (Net Cont: Bacitracin 3.39 Kgs))	1 Number
2	Medical Creams & Ointments(Bacitracin Zinc Ointment 1 OZ / 28 GM Tube Tot Wt: 7597.464Kgs (Net Cont: Bacitracin 64.27Kgs))	1 Number
3	Medical Creams & Ointments(Double Antibiotic Ointment 0.5 OZ / 14 GM Tube Tot Wt: 199.78Kgs (Net Cont: Bacitracin 1.69Kgs, Polymixin 0.37Kgs))	1 Number
4	Medical Creams & Ointments(Double Antibiotic Ointment 1 OZ / 28 GM tube Tot Wt: 1799.7Kgs (Net Cont: Bacitracin 15.23Kgs, Polymixin 3.29Kgs))	1 Number
5	Medical Creams & Ointments(Triple Antibiotic Ointment W/ Pramoxine HCL 0.2 OZ / 14 GM Tube Tot Wt: 2449.3Kgs (Net Cont: Baci 20.72Kgs, Poly 4.48Kgs, Neo 17.14Kgs, Pramo 24.98Kgs))	1 Number
6	Medical Creams & Ointments(Triple Antibiotic Ointment 0.5 OZ / 14 Gm Tube Tot Wt: 1213.59Kgs (Net Cont: Baci 7.77Kgs, Poly 1.03Kgs, Neo 8.49Kgs))	1 Number
7	Medical Creams & Ointments(Triple Antibiotic Ointment 1 OZ / 28 Gm Tube Tot Wt: 785.82Kgs (Net Cont: Baci 6.65Kgs, Poly 1.44Kgs, Neo 5.50Kgs))	1 Number
8	Medical Creams & Ointments(Triple MS Antibiotic Ointment 1 OZ / 28 Gm Tube Tot Wt: 1260Kgs (Net Cont: Baci 10.66Kgs, Poly 2.31Kgs, Neo 8.82Kgs))	1 Number
9	Medical Creams & Ointments(Triple MS Antibiotic Ointment 0.5 OZ / 14 Gm TubeTot Wt: 350Kgs (Net Cont: Baci 2.96Kgs, Poly 0.64Kgs, Neo 2.45Kgs))	1 Number
10	Medical Creams & Ointments(Triple MS Antibiotic Ointment 2 OZ / 56 Gm Tube Tot Wt: 392Kgs (Net Cont: Baci 3.32Kgs, Poly 0.72Kgs, Neo 2.74Kgs))	1 Number
11	Medical Creams & Ointments(Triple Antibiotic Ointment W/ Pramoxine HCL 1 OZ / 28 GM Tube Tot Wt: 560Kgs (Net Cont: Baci 4.74Kgs, Poly 1.02Kgs, Neo 3.92Kgs, Pramo 5.71Kgs))	1 Number
12	Medical Creams & Ointments(Triple Antibiotic Ointment W/ Pramoxine HCL 2 OZ / 56 GM Tube Tot Wt: 992.04Kgs (Net Cont: Baci 8.81Kgs, Poly 1.91Kgs, Neo 7.29Kgs, Pramo 10.62Kgs))	1 Number
Sl. No.	Import Items	Quantity allowed.

1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy

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

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

Case No.	71 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000633AM23
RA File Number	07AX04000046 AM23
Licence No and Date	0711003906/06/05/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
L-ORNITHINE-L-ASPARTATE (Pure-pharma)	8.0 MT	1	L-ORNITHINE-L-ASPARTATE (TECHNICAL GRADE)	8.08 MT

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

Case No.	72 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000635AM23
RA File Number	07AX04000115 AM23
Licence No and	0711003928/06/05/2022

Date	
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:- Complete Technical Details as per Annexure to Appendix-4E.	

Case No.	73 / NC/3/MEET/Nov/202324/16													
Case Status	Case Approved													
Party Name	ALEOR DERMACEUTICALS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023													
HQ File Number	HQRNORM APPLY 00000750AM23													
RA File Number	34AX04000127 AM23													
Licence No and Date	3411002246/13/05/2022													
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <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>FOAM(MINOXIDIL TOPICAL AEROSOL 5% (FOAM) 60 G CAN)</td> <td>1Number</td> <td>1</td> <td>MINOXIDIL USP</td> <td>3.06 gm.</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.	FOAM(MINOXIDIL TOPICAL AEROSOL 5% (FOAM) 60 G CAN)	1Number	1	MINOXIDIL USP	3.06 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
FOAM(MINOXIDIL TOPICAL AEROSOL 5% (FOAM) 60 G CAN)	1Number	1	MINOXIDIL USP	3.06 gm.										

Case No.	74 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	ANUH PHARMA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM APPLY 00000796AM23			
RA File Number	03AX04000377 AM23			
Licence No and Date	0311014743/17/05/2022			
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Erythromycin 11,12 Carbonate IP/BP/EP/USP	1 kg.	1	Erythromycin Thiocyanate	1.22 kgA
		2	Ethylene Carbonate	0.975 kg.

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

Case No.	75 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	SHIVA BIO CHEM INDUSTRIES			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM APPLY 00000856AM23			
RA File Number	50AX04000018 AM23			
Licence No and Date	5011000486/18/05/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Soya Lecithin Powder	1 MT	1	Soya Lecithin Liquid	1.40 MT

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

Case No.	76 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	VISION DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000893AM23
RA File Number	09AX04000124 AM23
Licence No and Date	0911003032/20/05/2022
Norms Committee Decision:	

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

Case No.	77 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	METROPOLITAN EXIMCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000920AM23
RA File Number	03AX04000550 AM23
Licence No and Date	0311014915/22/05/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	78 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM APPLY 00000944AM23			
RA File Number	09AX04000145 AM23			
Licence No and Date	0911003039/23/05/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
RUFINAMIDE	1 kg.	1	2 6 DIFLUORO BENZYL BROMIDE 2BROMOMETHYL 1 3 DIFLUORO BENZENE	1.35 kg.
		2	METHYL PROPIOLATE	0.66 kg.

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

Case No.	79 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023

and Date	
HQ File Number	HQRNORM REVIW00003358AM24
RA File Number	30AX04000065 AM23
Licence No and Date	3011002150/23/05/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	80 / NC/3/MEET/Nov/202324/16																
Case Status	Case Approved																
Party Name	HETERO DRUGS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023																
HQ File Number	HQRNORM APPLY 00000975AM23																
RA File Number	09AX04000080 AM23																
Licence No and Date	0911003042/25/05/2022																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td rowspan="2">NEBIVOLOL HYDROCHLORIDE</td><td rowspan="2">1 kg.</td><td>1</td><td>4-FLUORO PHENOL</td><td>5.037 kg.</td></tr><tr><td>2</td><td>DIBAH 25 % IN TOLUENE</td><td>18.02 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	NEBIVOLOL HYDROCHLORIDE	1 kg.	1	4-FLUORO PHENOL	5.037 kg.	2	DIBAH 25 % IN TOLUENE	18.02 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
NEBIVOLOL HYDROCHLORIDE	1 kg.	1	4-FLUORO PHENOL	5.037 kg.													
		2	DIBAH 25 % IN TOLUENE	18.02 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	81 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000976AM23
RA File Number	09AX04000136 AM23
Licence No and Date	0911003043/25/05/2022
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
FLECAINIDE ACETATE	1 kg.	1	2,2,2- Trifluoroethanol	0.917 kg.
		2	2,5- Bis (2,2,2-trifluoro ethoxy) benzoic Acid	1.084 kg.
		3	2-(Aminomethyl) piperidine	0.390 kg.

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

Case No.	82 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000978AM23
RA File Number	09AX04000133 AM23
Licence No and Date	0911003044/25/05/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
FLUVOXAMINE MALEATE	1 KG	1	5 METHOXY 1 4 TRIFLUORO METHYL PHENYL 1 PENTANONE	0.99 kg
		2	DIMETHYL FORMAMIDE	1.98 kg
		3	2 CHLOROETHYLAMINE HCL	0.48 kg
		4	SODIUM HYDROXIDE MICRO PEARLS	1.313 kg

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

Case No.	83 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00000980AM23
RA File Number	03AX04000822 AM23
Licence No and Date	0311014992/25/05/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	84 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	DHANUKA LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM APPLY 00000987AM23			
RA File Number	05AX04000414 AM23			
Licence No and Date	0511012794/25/05/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TELMISARTAN CRUDE (POWDER)	1 kg.	1	2-n-propyl-4-methyl-6-(1-methylbenzimidazol-2-yl)	0.57 kg.
		2	2-Cyano-4-Methyl Biphenyl (OTBN)	0.65 kg.
		3	Acetic Acid	0.824 kg.
		4	Toluene	1.57 kg.
		5	Methylene Chloride	1.83 kg.

		6	Methanol	1.83 kg.
RA concerned may take further necessary action as per above decision of NC				

Case No.	85 / NC/3/MEET/Nov/202324/16													
Case Status	Case Approved													
Party Name	MICRO LABS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023													
HQ File Number	HQRNORM APPLY 00001002AM23													
RA File Number	07AX04000209 AM23													
Licence No and Date	0711004103/26/05/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>PHLOROGLUCINOL VIATRIS 160 mg ODT (BP/EP/USP/IP 560 KG)</td><td>1 Number</td><td>1</td><td>PHLOROGLUCINOL DIHYDRATE</td><td>163.20 mg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PHLOROGLUCINOL VIATRIS 160 mg ODT (BP/EP/USP/IP 560 KG)	1 Number	1	PHLOROGLUCINOL DIHYDRATE	163.20 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
PHLOROGLUCINOL VIATRIS 160 mg ODT (BP/EP/USP/IP 560 KG)	1 Number	1	PHLOROGLUCINOL DIHYDRATE	163.20 mg										
RA concerned may take further necessary action as per above decision of NC														

Case No.	86 / NC/3/MEET/Nov/202324/16		
Case Status	Case Approved		
Party Name	ENCUBE ETHICALS PRIVATE LIMITED		
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023		
HQ File Number	HQRNORM APPLY 00001061AM23		
RA File Number	03AX04000415 AM23		
Licence No and Date	0311015092/30/05/2022		
Norms Committee Decision:			
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-			
Sl. No.	Export Product		Quantity

1	Medical Creams & Ointments(Permethrin Cream 5 % (60 Gm) Tot Wt: 37998.48 Kgs (Net Cont: Medium chain 3799.85 Kgs, Mono 1899.93Kgs, Isopropyl 379.99Kgs, Lanolin 569.98Kgs, Polyoxy 1519.94Kgs, Tubes 633308Nos))	1 Number
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Sl. No.	Import Items	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy

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

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

Case No.	87 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00004512AM24
RA File Number	03AX04000506 AM23
Licence No and Date	0311015097/30/05/2022
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Complete chemistry giving of both Acetic acid and Acetic Anhydride (indicating number moles in the reaction).	

Case No.	88 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ZENFOLD SUSTAINABLE TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023

HQ File Number	HQRNORM APPLY 00001090AM23
RA File Number	09AX04000132 AM23
Licence No and Date	0911003083/31/05/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	89 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	AMI ORGANICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM APPLY 00001128AM23			
RA File Number	52AX04000054 AM23			
Licence No and Date	5211002565/01/06/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Methyl Paraben Sodium	1 kg.	1	ParaHydroxy Benzoic Acid	0.934 kg.
		2	Methanol	0.99 kg.

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

Case No.	90 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001173AM23
RA File Number	03AX04001017 AM23
Licence No and Date	0311015227/03/06/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2,3 DI CHLORO PYRIDINE	240000.0 kg.	1	3 AMINO PYRIDINE	240000.0 kg.
		2	HYDROGEN PEROXIDE	152880.0 kg.
		3	SODIUM NITRITE	164880.0 kg.
		4	CAUSTIC SODA LYE (SODIUM HYDROXIDE LYE)	1519200.0 kg.

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

Case No.	91 / NC/3/MEET/Nov/202324/16													
Case Status	Case Approved													
Party Name	OC SPECIALITIES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023													
HQ File Number	HQRNORM REVIW00000271AM24													
RA File Number	03AX04001018 AM23													
Licence No and Date	0311015240/03/06/2022													
Norms Committee Decision:														
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under.														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Dimethyl-2-methyl glutarate (MGDM)</td><td>1 kg.</td><td>1</td><td>2-methyl glutaronitrile Crude</td><td>0.95 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Dimethyl-2-methyl glutarate (MGDM)	1 kg.	1	2-methyl glutaronitrile Crude	0.95 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Dimethyl-2-methyl glutarate (MGDM)	1 kg.	1	2-methyl glutaronitrile Crude	0.95 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	92 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	ENCUBE ETHICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			

HQ File Number	HQRNORM APPLY 00001229AM23
RA File Number	03AX04000530 AM23
Licence No and Date	0311015288/07/06/2022

Norms Committee Decision:

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

Sl. No.	Export Product	Quantity
1	Medical Cream & Ointment(CLOTRIMAZOLE 1% (10MG/G) VAGINAL CREAM 35 Gm Tot Wt 1360.10Kgs (Net Cont Clotri 13.60 Kgs, Cetyl 54.40Kgs,Octy40.80Kgs,Ceto108.81 Kgs, Tubes38860 Nos.))	1 Number
2	Medical Cream & Ointment(CLOTRIMAZOLE 1% (10MG/G) ANTI FUNGAL CREAM 50 Gm Tot Wt 5650 Kgs (Net Cont Clotri 56.50 Kgs, Cetyl 226Kgs,Octy169.50Kgs,Ceto452Kgs, Tubes 113000 Nos.))	1 Number
3	Medical Cream & Ointment(CLOTRIMAZOLE 1% ANTIFUNGAL CREAM 20Gm DUO Tot Wt 3780 Kgs (Net Cont Clotri 37.80 Kgs, Cetyl 151.20Kgs,Octy113.40Kgs,Ceto302.40 Kgs, Tubes 189000Nos))	1 Number

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

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

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

Case No.	93 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023

HQ File Number	HQRNORM APPLY 00001238AM23
RA File Number	03AX04000996 AM23
Licence No and Date	0311015308/07/06/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Beclometasone Pressurised Inhalation BP 50mcg/Actuation (200 MD)((Net Wt. of Zephex 134a /Norflurane (1,1,1,2-Tetrafluoroethane is Qty.983.98 kg))	100000.0 Number	1	ZEPHEX 134A NORFLURANE (1,1,1,2-TETRAFLUOROETHANE)	/1003.66 kg
Beclometasone Pressurised Inhalation BP100mcg/Actuation (200 MD)((Net Wt. of Zephex 134a/ Norflurane (1,1,1,2-Tetrafluoroethane is Qty.982.98 kg))	100000.0 Number	2	ZEPHEX 134A NORFLURANE (1,1,1,2-TETRAFLUOROETHANE)	/1002.64 kg
Beclometasone Pressurised Inhalation BP 200mcg/Actuation (200 MD)((Net Wt. of Zephex 134a/ Norflurane (1,1,1,2-Tetrafluoroethane is Qty.969.48 kg))	100000.0 Number	3	ZEPHEX 134A NORFLURANE (1,1,1,2-TETRAFLUOROETHANE)	/988.87 kg
Beclometasone Pressurised Inhalation BP 250mcg/Actuation (200 MD)((Net Wt. of Zephex 134a/ Norflurane (1,1,1,2-Tetrafluoroethane is Qty.956.97 kg))	100000.0 Number	4	ZEPHEX 134A NORFLURANE (1,1,1,2-TETRAFLUOROETHANE)	/976.11 kg
Ciclesonide Pressurised Inhalation Solution 80 mcg (120 MD)((Net Wt. of Zephex 134a/ Norflurane (1,1,1,2-Tetrafluoroethane is Qty.903.76 kg))	137200.0 Number	5	ZEPHEX 134A NORFLURANE (1,1,1,2-TETRAFLUOROETHANE)	/921.84 kg
Ciclesonide Pressurised Inhalation Solution 160 mcg (120 MD)((Net Wt. of Zephex 134a/ Norflurane (1,1,1,2-Tetrafluoroethane is Qty. 898.59 kg))	137200.0 Number	6	ZEPHEX 134A NORFLURANE (1,1,1,2-TETRAFLUOROETHANE)	/916.56 kg
Ciclesonide Pressurised Inhalation Solution 160 mcg (60 MD)((Net Wt. of Zephex 134a/ Norflurane (1,1,1,2-Tetrafluoroethane is Qty. 458.27 kg))	137200.0 Number	7	ZEPHEX 134A NORFLURANE (1,1,1,2-TETRAFLUOROETHANE)	/458.27 kg

Tetrafluoroethane is Qty.449.29 kg))				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	94 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	EAST AFRICAN INDIA OVERSEAS
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001260AM23
RA File Number	05AX04000587 AM23
Licence No and Date	0511013087/08/06/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NIPARIN INJECTION (HEPARIN INJECTION 5000IU/ML EACH VIAL OF 5ML)	51000 Pieces	1	Heparin Sodium IP	1300 MIU

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

Case No.	95 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001271AM23
RA File Number	09AX04000171 AM23
Licence No and Date	0911003148/08/06/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-(2-(2-(6,6-dimethylbicyclo [3.1.1] heptan-2-yl)ethoxy)ethyl) morpholine	1 Kg	1	DIHYDRONOPOL	0.66 kg
		2	TOLUENE	1.915 kg

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

Case No.	96 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	NATCO PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM REVIW00004490AM24
RA File Number	09AX04000174 AM23
Licence No and Date	0911003150/08/06/2022
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 information / documents.	

Case No.	97 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	NASENSE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001297AM23
RA File Number	09AX04000213 AM23
Licence No and Date	0911003160/09/06/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	98 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001340AM23
RA File Number	03AX04000749 AM23

Licence No and Date	0311015456/13/06/2022	
Norms Committee Decision:		
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-		
Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 10 Gm tubeLabelled content Clotrimazole 1 Percentage W/W Brand Canesten or any other. Tot Wt. 7320 Kgs (Net Cont: Clotri 73.20Kgs, Oct 988.20Kgs, Cetyl 219.60Kgs, Ceto 732Kgs, Emp tubes 732000Nos))	1 Number
2	Medical Creams & Ointments(Clotrimazole 1 Percentage Vaginal cream 35Gm Tube with 6 ApplicatorLabelled content Clotrimazole1 Percentage W/W Brand Canesten or any other Tot Wt. 1999.90Kgs (Net Cont: Clotri 20Kgs, Oct 269.99Kgs, Cetyl 60Kgs, Ceto 199.99Kgs, Emp tubes 57140Nos,)	1 Number
3	Medical Creams & Ointments(Clotrimazole1 PercentageCream 100 Gm Tube Labelled content Clotrimazole1 Percentage W/W Brand Canesten or any other Tot Wt. 1000Kgs (Net Cont: Clotri 10Kgs, Oct 135Kgs, Cetyl 30Kgs, Ceto 100Kgs, Emp tubes 10000Nos))	1 Number
4	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 20Gm.Tube Labelled content Clotrimazole1 PercentageW/W Brand Canesten or any other Tot Wt. 11140Kgs (Net Cont: Clotri 111.40Kgs, Oct 1503.90Kgs, Cetyl 334.20Kgs, Ceto 1114Kgs, Emp tubes 557000Nos))	1 Number
5	Medical Creams & Ointments(Clotrimazole 1 PercentageCream 50 Gm.Tube Labelled content Clotrimazole1 PercentageW/W Brand Canesten or any other. Tot Wt. 8440Kgs (Net Cont: Clotri 84.40Kgs, Oct 1139.40Kgs, Cetyl 253.20Kgs, Ceto 844Kgs, Emp tubes 168800Nos))	1 Number
6	Medical Creams & Ointments(Clotrimazole 2 Percentage Vaginal Cream 20 Gm.Tube with 3 ApplicatorLabelled content Clotrimazole 2 PercentageW/W Brand Canesten or any other. Tot Wt. 2000Kgs (Net Cont: Clotri 40Kgs, Oct 270Kgs, Cetyl 60Kgs, Ceto 200Kgs, Emp100000Nos, Appl 300000Nos)	1 Number
7	Medical Creams & Ointments(Clotrimazole10 PercentageVaginal cream 5 Gm Tube with 1 Applicator. Labelled content Clotrimazole 10 Percentage W/W;Brand Canesten or any other Tot Wt. 100Kgs (Net Cont: Clotri 10Kgs, Cetyl 3Kgs, Ceto 3.50Kgs, Emp tubes 20000Nos, Applicator 20000Nos))	1 Number
8	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 5 Gm.Tube Labelled content Clotrimazole 1 Percentage W/W Brand Canesten or any other. Tot Wt. 1250Kgs (Net Cont: Clotri 12.500Kgs, Oct 236.25Kgs, Cetyl 52.50Kgs, Ceto 175Kgs, Emp tubes 350000Nos))	1 Number
9	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 3 Gm. Tube Labelled content Clotrimazole 1 Percentage W/W Brand Canesten or any other Tot Wt. 1500Kgs (Net Cont: Clotri 15Kgs, Oct 202.50Kgs, Cetyl 45Kgs, Ceto 150Kgs, Emp tubes 500000Nos))	1 Number

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

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

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

Case No.	99 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001345AM23
RA File Number	05AX04000761 AM23
Licence No and Date	0511013170/13/06/2022

Norms Committee Decision:

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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.
Ofloxacin Otic Solution, 5ml(Having net content of 5.83 kg of Bulk Drug), 0.3 % w/v	1 Number	1	OFLOXACIN USP	15.30 mg
Ofloxacin Otic Solution, 10ml(Having net content of 4.01 kg of Bulk Drug), 0.3 % w/v	1 Number	2	OFLOXACIN USP	30.60 mg
Ofloxacin Ophthalmic Solution, USP, 5ml(Having net content of 13.22 kg of Bulk	1 Number	3	OFLOXACIN USP	15.30 mg

Drug), 0.3 % w/v				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	100 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001346AM23
RA File Number	05AX04000760 AM23
Licence No and Date	0511013171/13/06/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No.0511017985 dated 24/03/2023** , 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.
Tobramycin Inhalation Solution, USP, 300mg/ 4ml(Having net content of 45.78 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.	101 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001347AM23
RA File Number	05AX04000669 AM23
Licence No and Date	0511013173/13/06/2022

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:-

1. **Stoichiometric balance between import and export on molar basis.**
2. **Application/function of each Chemical in the process with justification.**
3. **Indigenous items to use in the process and accordingly to fill Appendix-4E Annexure.**
4. **Commercial value of the by-product, if any, and details of norms fined by Committee in past.**

Case No.	102 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001358AM23
RA File Number	03AX04001122 AM23
Licence No and Date	0311015470/13/06/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	103 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001399AM23
RA File Number	03AX04001167 AM23
Licence No and Date	0311015523/15/06/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	104 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001459AM23
RA File Number	07AX04000281 AM23
Licence No and Date	0711004347/17/06/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export	

product/import product in meeting **No.13/82-ALC4/2019 dated 31/01/2019** against advance authorization **No. 0710114345 dated 31/12/2018**, 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.
MAGNESIUM ASPARTATE (BP /DIHYDRATE Eur.Ph)	1 kg.	1	L-ASPARTIC ACID	1.05 kg.

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

Case No.	105 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001604AM23
RA File Number	08AX04000401 AM23
Licence No and Date	0811005305/23/06/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Oct/202324/15 dated 13.10.2023** against advance authorization **No. 0811002958 dated 22.10.2021**, 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.
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 1ML VIAL(EACH ML CONTAINS: VINORELBINE TARTRATE PH.EUR EQ. TO VINORELBINE 10 MG)	1 Number	1	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR (Water content 2.3 %)	14.33 mg
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 5ML VIAL(EACH ML CONTAINS: VINORELBINE	1 Number	2	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR (Water content 2.3 %)	71.66 mg

TARTRATE PH.EUR EQ. TO VINOELBINE 10 MG [IN WHICH ACTIVE INGREDIENT VINOELBINE TARTRATE USED IS 813.000 GRAMS])				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	106 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001605AM23
RA File Number	08AX04000497 AM23
Licence No and Date	0811005314/23/06/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	107 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	BEST VALUE CHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM APPLY 00001745AM23			
RA File Number	34AX04000259 AM23			
Licence No and Date	3411002449/29/06/2022			
Norms Committee Decision:				
Dr. Dhaval Patel, Technical Expert, Shri Dhruval Parmar (Exim) of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Undecavertol (Kakdinol)	1 kg.	1	Propionaldehyde	0.947 kg.

(4-Methyl-3-decen- 5-ol))		2	1-Pentanol / N Amyl Alcohol	0.709 kg.
		3	Magnesium Turning	0.182 kg.

Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms.

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

Case No.	108 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001817AM23
RA File Number	03AX04001952 AM23
Licence No and Date	0311016049/04/07/2022

Norms Committee Decision:

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

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(HYDROCORTISONE VALERATE CRM 0.2% 15GM Tot Wt: 225Kgs (Net Cont: Hyd 0.45Kgs, Carbo 1.13Kgs, Dibasic 0.14Kgs, Methyl 0.45Kgs, Sodium 0.27Kgs, Polyoxyl 9Kgs, Polyoxylethylene 0.72Kgs, Stearyl 6.75Kgs, Super 51.75Kgs, Propylene 36Kgs, Tubes 15000Nos))	1 Number
2	Medical Creams & Ointments(HYDROCORTISONE VALERATE CRM 0.2% 45GM Tot Wt: 450Kgs (Net Cont: Hyd 0.90Kgs, Carbo 2.25Kgs, Dibasic 0.27Kgs, Methyl 0.90Kgs, Sodium 0.54Kgs, Polyoxyl 18Kgs, Polyoxylethylene 1.44Kgs, Stearyl 13.50Kgs, Super 103.5Kgs, Propylene 72Kgs, Tubes 10000Nos))	1 Number
3	Medical Creams & Ointments(HYDROCORTISONE VALERATE CRM 0.2% 60GM Tot Wt: 360Kgs (Net Cont: Hyd 0.72Kgs, Carbo 1.80Kgs, Dibasic 0.22Kgs, Methyl 0.72Kgs, Sodium 0.43Kgs, Polyoxyl 14Kgs, Polyoxylethylene 1.15Kgs, Stearyl 10.80Kgs, Super 82.80Kgs, Propylene 57.6Kgs, Tubes 6000Nos))	1 Number

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

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

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

Case No.	109 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001837AM23
RA File Number	03AX04001983 AM23
Licence No and Date	0311016079/04/07/2022

Norms Committee Decision:

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

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Miconazole Nitrate 2 % Antifungal Cream 0.5 Oz / 14 Gm Tot Wt: 394.8 Kgs (Net Cont: Benzoic 0.79 Kgs, Pegoxyl 78.99 Kgs, Oleoyl 11.87 Kgs, Miconazole 8.19 Kgs))	1 Number
2	Medical Creams & Ointments(Miconazole Nitrate 2 % Antifungal Cream 1 Oz / 28 Gm Tot Wt: 4809.7 Kgs (Net Cont: Benzoic 9.62 Kgs, Pegoxyl 962.28 Kgs, Oleoyl 144.64 Kgs, Miconazole 99.75 Kgs))	1 Number
3	Medical Creams & Ointments(Miconazole Nitrate 2 % Antifungal Cream 1.5 Oz / 42.5 Gm Tot Wt: 794.33 Kgs (Net Cont: Benzoic 1.59 Kgs, Pegoxyl 158.92 Kgs, Oleoyl 23.89 Kgs, Miconazole 16.47 Kgs))	1 Number
4	Medical Creams & Ointments(Miconazole Nitrate 2 % Vaginal Cream USP 1.59 Oz / 45 Gm	1 Number

	with 1 Applicator Pack Tot Wt: 3421.40 Kgs (Net Cont: Benzoic 6.84 Kgs, Pegoxyl 684.52 Kgs, Oleoyl 102.89 Kgs, Miconazole 70.96 Kgs, Plas App 76031 Nos))	
5	Medical Creams & Ointments(Miconazole Nitrate 2 % Vaginal Cream USP 1.59 Oz / 45 Gm with 7 Applicator Pack Tot Wt: 35599.59 Kgs (Net Cont: Benzoic 71.20 Kgs, Pegoxyl 7122.41 Kgs, Oleoyl 1070.55 Kgs, Miconazole 738.34 Kgs, Plas App 791102 Nos))	1 Number

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

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

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

Case No.	110 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001959AM23
RA File Number	03AX04002151 AM23
Licence No and Date	0311016241/11/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	111 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001963AM23
RA File Number	05AX04001045 AM23

Licence No and Date	0511013693/11/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	112 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001993AM23
RA File Number	34AX04000353 AM23
Licence No and Date	3411002522/12/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	113 / NC/3/MEET/Nov/202324/16	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023	
HQ File Number	HQRNORM APPLY 00001998AM23	
RA File Number	03AX04002023 AM23	
Licence No and Date	0311016305/12/07/2022	
Norms Committee Decision:		
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-		
Sl. No.	Export Product	Quantity
1	Medical creams & Ointment (TRETINOIN MICROSPHERE TOPICAL GEL 0.08% 50ML PUMP Tot Wt:2500 Kg Net cont:TRETI 2.20Kg PROP55 Kg BUTY0.25Kg ACRY162.5Kg EDET0.25Kg CARB 974P22.50Kg GLYC312.5Kg SORB4.50Kg PPG20 118.75Kg CYCLO57.5Kg BENZ25Kg TROL10 Kg PROP 50Kg BOT50000 No PUM 5000No)	1 Number
Sl. No.	Import Items	Quantity allowed.

1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy

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

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

Case No.	114 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001999AM23
RA File Number	03AX04002195 AM23
Licence No and Date	0311016306/12/07/2022

Norms Committee Decision:

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

Sl. No.	Export Product	Quantity
1	Medical creams & Ointment(Fluocinolone Acetonide Topical Solution USP 0.01 % (60 ML) Tot Wt: 12300 Kgs (Net Cont: Fluocinolone 1.23 Kgs, 2 Oz. White HDPE 205000 Nos, White PP dropper 205000 Nos, 20MM Natural LLDPE 205000Nos))	1 Number

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

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

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

Case No.	115 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002011AM23
RA File Number	52AX04001578 AM23
Licence No and Date	5211002817/13/07/2022

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:-

- i. **Details of items/application Methylene chloride and Methanol in the process and justify the high requirement of these two.**
- ii. **Yield of the reaction and giving calculation for the requirement of all the chemicals.**
- iii. **Production/consumption data for the last three years duly endorsed by GST/CA.**

Case No.	116 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002017AM23
RA File Number	09AX04000301 AM23
Licence No and Date	0911003338/13/07/2022

Norms Committee Decision:

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

Case No.	117 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002018AM23

RA File Number	09AX04000333 AM23
Licence No and Date	0911003339/13/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	118 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002019AM23
RA File Number	09AX04000338 AM23
Licence No and Date	0911003340/13/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	119 / NC/3/MEET/Nov/202324/16																
Case Status	Case Approved																
Party Name	FRESENIUS KABI ONCOLOGY LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023																
HQ File Number	HQRNORM APPLY 00002039AM23																
RA File Number	05AX04001046 AM23																
Licence No and Date	0511013764/14/07/2022																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Aug/202324/11 dated 22.08.2023 against advance authorization No. 0511006367 dated 23.11.2021 , 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:-																	
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td rowspan="2">Docetaxel Trihydrate (Anti cancer bulk drug)</td><td rowspan="2">1 kg</td><td>1</td><td>Taxus Baccatta Leaves</td><td>1340 kg</td></tr><tr><td>2</td><td>DSC -9 [4S,5R)-2-(4-methoxyphenyl)-N-t-boc-phenyl-oxazolidine-5-carboxylic acid]</td><td>0.888 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Docetaxel Trihydrate (Anti cancer bulk drug)	1 kg	1	Taxus Baccatta Leaves	1340 kg	2	DSC -9 [4S,5R)-2-(4-methoxyphenyl)-N-t-boc-phenyl-oxazolidine-5-carboxylic acid]	0.888 kg
Export Product	Qty.	Sl. No.	Import Items	Qty.													
Docetaxel Trihydrate (Anti cancer bulk drug)	1 kg	1	Taxus Baccatta Leaves	1340 kg													
		2	DSC -9 [4S,5R)-2-(4-methoxyphenyl)-N-t-boc-phenyl-oxazolidine-5-carboxylic acid]	0.888 kg													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	120 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002067AM23
RA File Number	34AX04000361 AM23
Licence No and Date	3411002535/15/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	121 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002087AM23
RA File Number	09AX04000341 AM23
Licence No and Date	0911003356/15/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	122 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	SYMBIOTEC PHARMALAB PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002133AM23
RA File Number	56AX04000094 AM23
Licence No and Date	5611001068/19/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	123 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002158AM23

RA File Number	07AX04000582 AM23
Licence No and Date	0711004714/20/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	124 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002174AM23
RA File Number	03AX04002330 AM23
Licence No and Date	0311016485/21/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	125 / NC/3/MEET/Nov/202324/16													
Case Status	Case Approved													
Party Name	JUBILANT INGREVIA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023													
HQ File Number	HQRNORM APPLY 00002179AM23													
RA File Number	05AX04001164 AM23													
Licence No and Date	0511013888/21/07/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<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">Propionic Anhydride</td><td rowspan="2">1 kg.</td><td>1</td><td>Propionic Acid</td><td>1.41 kg.</td></tr><tr><td>2</td><td>Acetic Acid Glacial</td><td>0.50 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Propionic Anhydride	1 kg.	1	Propionic Acid	1.41 kg.	2	Acetic Acid Glacial	0.50 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Propionic Anhydride	1 kg.	1	Propionic Acid	1.41 kg.										
		2	Acetic Acid Glacial	0.50 kg.										
RA concerned may take further necessary action as per above decision of NC														

Case No.	126 / NC/3/MEET/Nov/202324/16
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Case Status	Case Deferred
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002187AM23
RA File Number	09AX04000313 AM23
Licence No and Date	0911003379/21/07/2022
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:- 1. Export product description in agenda and in the CA certificate and Appendix 4E is mismatch. Please clarify.	

Case No.	127 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
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:- 1. To give Chemistry of the reaction indicating molecular weight of both reactant band product. 2. Yield of the reaction with end uses of the export item.	

Case No.	128 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002228AM23
RA File Number	03AX04002208 AM23
Licence No and Date	0311016558/25/07/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	129 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ASMEE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002262AM23
RA File Number	03AX04002314 AM23
Licence No and Date	0311016599/26/07/2022
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:- 1. To give complete chemical reaction indicating molecular weight of each chemicals with chemical formula (not using abbreviation) 2. Yield of the reaction with justification. 3. By-product, if any, with its commercial value.	

Case No.	130 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	FDC LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM APPLY 00002269AM23			
RA File Number	03AX04002211 AM23			
Licence No and Date	0311016614/26/07/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
OFLOXACIN OTIC SOLUTION 5 ML((EACH VIAL CONTAINS OFLOXACIN 0.015 GM NET WT OF BULK DRUG IS 2.25 KGS))	1 Number	1	OFLOXACIN	15.30 mg
OFLOXACIN OTIC SOLUTION 10 ML((EACH VIAL CONTAINS OFLOXACIN 0.03 GM NET WT OF BULK DRUG IS 2.25 KGS))	1 Number	2	OFLOXACIN	30.00 mg

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

Case No.	131 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002280AM23
RA File Number	03AX04002424 AM23
Licence No and Date	0311016629/26/07/2022

Norms Committee Decision:

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

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Clindamycin Phosphate Topical Solution USP 1 % (60 ML) Tot Wt: 19530 Kgs (Net Cont: CLINDA 249.98Kgs, 2 Oz. HDPE 350000Nos, 24-400 WHITE PP 350000Nos, DAB-O-MATIC 350000Nos.))	1 Number
2	Medical Creams & Ointments(Clindamycin Phosphate Topical Solution USP 1 % (30 ML) Tot Wt: 3069 Kgs (Net Cont: CLINDA 39.28Kgs, 1 Oz. HDPE 110,000Nos, 24-400 WHITE PP 110,000Nos, DAB-O-MATIC 110,000Nos.))	1 Number
3	Medical Creams & Ointments(Clindamycin Phosphate & Benzoyl Peroxide Gel, 1.2%/5% (45 Gm) Tot Wt: 7499.93 Kgs (Net Cont: CLINDA 90 Kgs, HYDROUS BENZ 375 Kgs.Tubes 166665Nos))	1 Number
4	Medical Creams & Ointments(CLINDAMYCIN PHOSPHATE TOP. LOT. 1% 60ML Tot Wt: 26968.92 Kgs (Net Cont: CLINDA 320.40 Kgs, STEARIC ACID 539.39 Kgs, KOLLIWAX CSA674.23Kgs, LDPE BOTTLE483314 Nos))	1 Number
5	Medical Creams & Ointments(CLINDAMYCIN(PHOSPHATE) GEL30 Gm Tot Wt: 3999.84 Kgs (Net Cont: CLINDA 47.60Kgs, Tubes 133328Nos.))	1 Number
6	Medical Creams & Ointments(CLINDAMYCIN(PHOSPHATE) GEL60 Gm Tot Wt: 3999.84 Kgs (Net Cont: CLINDA 47.60Kgs, Tubes 66664 Nos.))	1 Number
7	Medical Creams & Ointments(Clindamycin 10mg/g + Benzoyl Peroxide 50mg/g Gel	1 Number

	30Gm Tot Wt: 1440 Kgs (Net Cont: CLINDA 14.40 Kgs, BENZOYL 72 Kgs, Tubes 48000 Nos))	
8	Medical Creams & Ointments(Clindamycin 10mg/g + Benzoyl Peroxide 50mg/g Gel 60 Gm Tot Wt: 1559.94 Kgs (Net Cont: CLINDA 15.60 Kgs, BENZOYL 111.38 Kgs, Tubes 25999 Nos))	1 Number

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

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

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

Case No.	132 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002282AM23
RA File Number	31AX04000121 AM23
Licence No and Date	3111001587/26/07/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 86.66% W/W WHITE	1 kg.	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.484 kg.

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

Case No.	133 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002284AM23
RA File Number	09AX04000361 AM23
Licence No and Date	0911003407/26/07/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Sep/202324/14 dated 27.09.2023** against advance authorization **No. 0911005558 dated 03.08.2023**, 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.
Tazobactam(Tazobactam Anhydrous)	1 kg	1	Acetone	12.23 kg
		2	BENZHYDRYL DIHYDROPENICILLANATE-1-OXIDE	6.6-6.38 kg
		3	Carbon Enoanticromos	0.200 kg
		4	Dimethylformamide (D M F)	18.87 kg
		5	Methanol (Methyl Alcohol)	3.09 kg
		6	Methylene Chloride	10.76 kg

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

Case No.	134 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002294AM23
RA File Number	09AX04000377 AM23
Licence No and Date	0911003411/27/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	135 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002317AM23
RA File Number	09AX04000364 AM23
Licence No and Date	0911003412/28/07/2022
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- i. Justification of low yield i.e. 72%. ii. Production/consumption data certified by GST for last one year.	

Case No.	136 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002358AM23
RA File Number	34AX04000398 AM23
Licence No and Date	3411002586/29/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	137 / NC/3/MEET/Nov/202324/16
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Case Status	Case Deferred
Party Name	RA CHEM PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002388AM23
RA File Number	09AX04000378 AM23
Licence No and Date	0911003424/01/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	138 / NC/3/MEET/Nov/202324/16													
Case Status	Case Approved													
Party Name	LEBEN LABORATORIES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023													
HQ File Number	HQRNORM APPLY 00002393AM23													
RA File Number	03AX04002517 AM23													
Licence No and Date	0311016775/01/08/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Apr/202223/1 dated 29/04/2021 against advance authorization No. 0311009732 dated 23.12.2021 , it was decided to ratify 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.</td></tr><tr><td>DOXYLEB CAPSULES (DOXYCYCLINE HYCLATE CAPSULES BP)100MG(IN PACKING OF 10sx10, 10sx100 & 1000s. QTY CONSUMED OF EXEMPT MATERIAL DOXYCYCLINE HYCLATE BP-117MG/CAPSULE)</td><td>7051282 Number</td><td>1</td><td>DOXYCYCLINE HYCLATE BP</td><td>813.72 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	DOXYLEB CAPSULES (DOXYCYCLINE HYCLATE CAPSULES BP)100MG(IN PACKING OF 10sx10, 10sx100 & 1000s. QTY CONSUMED OF EXEMPT MATERIAL DOXYCYCLINE HYCLATE BP-117MG/CAPSULE)	7051282 Number	1	DOXYCYCLINE HYCLATE BP	813.72 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
DOXYLEB CAPSULES (DOXYCYCLINE HYCLATE CAPSULES BP)100MG(IN PACKING OF 10sx10, 10sx100 & 1000s. QTY CONSUMED OF EXEMPT MATERIAL DOXYCYCLINE HYCLATE BP-117MG/CAPSULE)	7051282 Number	1	DOXYCYCLINE HYCLATE BP	813.72 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	139 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	S.V.CHEM INTERMEDIATES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023													
HQ File Number	HQRNORM APPLY 00002400AM23													
RA File Number	04AX04000404 AM23													
Licence No and Date	0411003747/02/08/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No. 0411004409 dated 07/11/2022 , 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>CBZ-L-Valine(CBZ-L-Valine)</td><td>1 kg.</td><td>1</td><td>L - Valine</td><td>0.50 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CBZ-L-Valine(CBZ-L-Valine)	1 kg.	1	L - Valine	0.50 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
CBZ-L-Valine(CBZ-L-Valine)	1 kg.	1	L - Valine	0.50 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	140 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	APTRA SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002435AM23
RA File Number	09AX04000268 AM23
Licence No and Date	0911003430/03/08/2022
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:- 1. Chemical reaction of making export item indicating stages where solvent is used. 2. Calculation for the requirement of solvent indicating quantity recycling to reuse. 3. Production/Consumption data duly endorsed by GST.	

Case No.	141 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	NIFTY LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002449AM23

RA File Number	09AX04000391 AM23
Licence No and Date	0911003436/03/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	142 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002474AM23
RA File Number	34AX04000434 AM23
Licence No and Date	3411002610/04/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	143 / NC/3/MEET/Nov/202324/16			
Case Status	Case Approved			
Party Name	NEULAND LABORATORIES LTD.			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023			
HQ File Number	HQRNORM APPLY 00001017AM24			
RA File Number	09AX04000149 AM24			
Licence No and Date	0911005088/22/05/2023			
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 No. NC/3/MEET/Jun/202324/8 dated 30/06/2023 against advance authorization No.0911004910 dated 28/04/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
IBREXAFUNGERP CITRATE	1 kg.	1	ENFUMAFUNGIN	4.55 kg.
RA concerned may take further necessary action as per above decision of NC				

Case No.	144 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved

Party Name	NEULAND LABORATORIES LTD.													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023													
HQ File Number	HQRNORM APPLY 00001148AM24													
RA File Number	09AX04000170 AM24													
Licence No and Date	0911005122/26/05/2023													
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.0911004910 dated 28/04/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>IBREXAFUNGERP CITRATE</td> <td>1 kg.</td> <td>1</td> <td>ENFUMAFUNGIN</td> <td>4.55 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.	IBREXAFUNGERP CITRATE	1 kg.	1	ENFUMAFUNGIN	4.55 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
IBREXAFUNGERP CITRATE	1 kg.	1	ENFUMAFUNGIN	4.55 kg.										

Case No.	145 / NC/3/MEET/Nov/202324/16													
Case Status	Case Approved													
Party Name	LEBEN LABORATORIES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023													
HQ File Number	HQRNORM APPLY 00001232AM24													
RA File Number	03AX04000970 AM24													
Licence No and Date	0311024107/01/06/2023													
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Apr/202223/1 dated 29/04/2022 against advance authorization No.0311009732 dated 23/12/2021, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table 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>DOXYLEB CAPSULE (DOXYCYCLINE HYCLATE CAPSULES BP) 100MG (IN PACKING OF 10x10s, 10 x 100s & 1000s. QTY CONSUMED OF EXEMPT</td> <td>9965338 Numbers</td> <td>1</td> <td>DOXYCYCLINE HYCLATE BP</td> <td>1150 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DOXYLEB CAPSULE (DOXYCYCLINE HYCLATE CAPSULES BP) 100MG (IN PACKING OF 10x10s, 10 x 100s & 1000s. QTY CONSUMED OF EXEMPT	9965338 Numbers	1	DOXYCYCLINE HYCLATE BP	1150 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
DOXYLEB CAPSULE (DOXYCYCLINE HYCLATE CAPSULES BP) 100MG (IN PACKING OF 10x10s, 10 x 100s & 1000s. QTY CONSUMED OF EXEMPT	9965338 Numbers	1	DOXYCYCLINE HYCLATE BP	1150 kg.										

MATERIAL DOXYCYCLINE HYCLATE BP-115.400MG/CAPSULE)				
RA concerned may take further necessary action as per above decision of NC				

Case No.	146 / NC/3/MEET/Nov/202324/16
Case Status	Case Deferred
Party Name	LOZEN PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001379AM24
RA File Number	03AX04001008 AM24
Licence No and Date	0311024330/07/06/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	147 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001436AM24
RA File Number	03AX04001014 AM24
Licence No and Date	0311024400/09/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC.3/MEET/Aug/202223/6 dated 09/09/2022** against advance authorization **No.0311009926 dated 30/12/2021**, 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.
Fenofibrate Bulk Granulate	1 kg.	1	Fenofibrate Micronized IH/Ph.Eur	0.3155 kg.
		2	Hypromellose (2910, 3 cps) Ph. Eur	0.0625 kg.
		3	Docusate Sodium Ph.Eur	0.0062 kg.

		4	Sucrose Ph.Eur	0.3124 kg.
		5	Sodium Lauril Sulfate Ph.Eur	0.0216 kg.
		6	Lactose Monohydrate Ph.Eur	0.2804 kg.

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

Case No.	148 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001707AM24
RA File Number	03AX04001130 AM24
Licence No and Date	0311024614/16/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/MEET/Mar/202122/15 dated 17/03/2022** against advance authorization **No.0311001453 dated 12/02/2021**, 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.
Tablets/Capsules namely Fenofibrate 145mg tablets) (70200000 NOS)Nos)(Net Content:1)10298.340 KGS 2) 10219.014 KGS 3) (Indi):2073.708KGS 4) (Indi):202.878KGS 5) (Indi):705.510KGS 6) (Indi):9170.226KGS 7) (Indi):5977.530KGS 8) (Indi):5242.536KGS 9) (Indi):63.180KGS 10)(Indi): 2084.940KGS)	1 kg.	1	Fenofibrate Micronized IH/Ph Eur	147.90 mg.
		2	Sucrose PH.Eur (exepient)	143.575 mg.

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

Case No.	149 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00001908AM24
RA File Number	09AX04000226 AM24
Licence No and Date	0911005228/19/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No.0911004910 dated 28/04/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
IBREXAFUNGERP CITRATE	1 kg.	1	ENFUMAFUNGIN	4.55 kg.

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

Case No.	150 / NC/3/MEET/Nov/202324/16
Case Status	Case Approved
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202324/ 16 and 17/11/2023
HQ File Number	HQRNORM APPLY 00002160AM24
RA File Number	03AX04001241 AM24
Licence No and Date	0311024825/23/06/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Chloroquine Phosphate (CQP)	1 kg.	1	NOVALDIAMINE	0.411 kg.

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