



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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(DES - III SECTION)**MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Oct/202324/15**DATED:** 13/10/2023Please 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/Oct/202324/15 dated 13/10/2023 of Norms Committee - III for the year 2023-24 was held on 13/10/2023 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/Oct/202324/15
Case Status	Case Deferred
Party Name	CYKLO PHARMA CHEM PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00003200AM24
RA File Number	032404000318 AM04
Licence No and Date	0310204913/29/05/2003
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. Molar Weight of each input and output item of each stage. ii. Percentage yield on molar basis for each step. iii. CA certified Production/Consumption data. iv. 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.	2 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	MOREPEN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00006470AM23
RA File Number	052404000420 AM14
Licence No and Date	0510378413/05/02/2014
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.	

Case No.	3 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	SHREE GANESH REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00003812AM23
RA File Number	342404000295 AM15
Licence No and Date	3410040965/16/02/2015

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.
Sorbyl Acetate	1 kg.	1	Sorbic Acid	1.429 kg.
		2	Vitride	3.045 kg.

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

Case No.	4 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	MOREPEN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00006437AM23
RA File Number	052404000073 AM16
Licence No and Date	0510394342/25/05/2015
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case.	

Case No.	5 / NC/3/MEET/Oct/202324/15	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023	
HQ File Number	HQRNORM REVIW00004115AM23	
RA File Number	039404001044 AM16	
Licence No and Date	0310803171/09/03/2016	
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	NYSTATIN AND TRIAMCINOLONE ACETONIDE CREAM USP 15 GM TUBE	1 Number
2	NYSTATIN AND TRIAMCINOLONE ACETONIDE CREAM USP 30 GM TUBE	1 Number
3	NYSTATIN AND TRIAMCINOLONE ACETONIDE CREAM USP 60 GM TUBE	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.	6 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	PARAMOUNT AROMACHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00001869AM23
RA File Number	052404000399 AM17
Licence No and Date	0510400599/02/12/2016

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.
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CARVACROL	27,500 kg	1	DIPENTENE	1,94,128 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.	7 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	PARAMOUNT AROMACHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00001867AM23
RA File Number	052404000008 AM18
Licence No and Date	0510402246/18/04/2017

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.
CARVACROL	59,300 kg.	1	DIPENTENE	3,95,727 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.	8 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	PARAMOUNT AROMACHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00001870AM23
RA File Number	052404000297 AM18
Licence No and	0510404439/31/10/2017

Date				
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.
CARVACROL	71,400 kg	1	DIPENTENE	1,41,700 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.	9 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00002756AM23
RA File Number	522404000085 AM18
Licence No and Date	5210042570/20/03/2018
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	10 / NC/3/MEET/Oct/202324/15			
Case Status	Case Approved			
Party Name	AUROBINDO PHARMA LTD			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM REVIW00006188AM23			
RA File Number	092404000168 AM19			
Licence No and Date	0910066418/04/07/2018			
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.

Cefepime for Injection 1000 mg (20ml Vial) (Each vial contains Sterile mixture of Cefepime Hydrochloride and L-Arginine equivalent to anhydrous Cefepime 1000 mg)	1 Number	1	Cefepime Hydrochloride (Non-sterile)	1.2428 gm
		2	L - Arginine	0.702 gm
		3	Acetone	1.8975 gm
		4	Isopropyl Alcohol	0.9488 gm
		5	Methanol	2.9812 gm
Cefepime for Injection 2000mg (50ml Vial) (Each vial contains Sterile mixture of Cefepime Hydrochloride and L-Arginine equivalent to anhydrous Cefepime 2000 mg)	1 Number	1	Cefepime Hydrochloride (Non-sterile)	2.4856 gm
		2	L - Arginine	1.404 gm
		3	Acetone	3.795 gm
		4	Isopropyl Alcohol	1.8976 gm
		5	Methanol	5.962 gm

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

Case No.	11 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00001184AM23
RA File Number	092404000181 AM19
Licence No and Date	0910066442/11/07/2018
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. Import Quantity for each export item not matching with DML in electronic format. Hard copy of Advance Authorisation may be called from the firm.

Case No.	12 / NC/3/MEET/Oct/202324/15
Case Status	Case Rejected
Party Name	CROPNOSYS (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00005535AM23
RA File Number	039404000527 AM19
Licence No and Date	0310823957/24/09/2018
Norms Committee Decision: Dr. Vijendra H. Pardeshi, Sr. Group Leader of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of the representative of the firm and after due deliberation, the committee rejected the request as found no ground as the export obligation period has already been expired.	

Case No.	13 / NC/3/MEET/Oct/202324/15																
Case Status	Case Approved																
Party Name	AUROBINDO PHARMA LTD																
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023																
HQ File Number	HQRNORM REVIW00006120AM23																
RA File Number	092404000345 AM19																
Licence No and Date	0910066762/25/10/2018																
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="3">AMOXYCILLIN AND CLAVULANATE POTASSIUM 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.</td><td rowspan="3">1 Number</td><td>1</td><td>6-APA</td><td>325.00 mg.</td></tr><tr><td>2</td><td>Methanol</td><td>18.717 mg.</td></tr><tr><td>3</td><td>Methyl d-(-)-4-hydroxy-phenylglycinate OR D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]</td><td>281.86 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	AMOXYCILLIN AND CLAVULANATE POTASSIUM 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.	1 Number	1	6-APA	325.00 mg.	2	Methanol	18.717 mg.	3	Methyl d-(-)-4-hydroxy-phenylglycinate OR D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]	281.86 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
AMOXYCILLIN AND CLAVULANATE POTASSIUM 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.	1 Number	1	6-APA	325.00 mg.													
		2	Methanol	18.717 mg.													
		3	Methyl d-(-)-4-hydroxy-phenylglycinate OR D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]	281.86 mg.													

		4	Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)	1.00 mg.
		5	Potassium Clavulanate diluted with Microcrystalline Cellulose (1:1) / Clavulanate Potassium +Avicel [in Active Base]	297.825 mg.

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

Case No.	14 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00006118AM23
RA File Number	092404000386 AM19
Licence No and Date	0910066874/20/11/2018

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.
AMOXYCILLIN AND CLAVULANATE POTASSIUM TABLETS 1000 MG (Each film coated Tablet contains: Amoxicillin Trihydrate equivalent to Anhydrous Amoxicillin 875 mg and Clavulanate Potassium equivalent to Clavulanic Acid 125 mg)		1	6-APA	581.77 mg.
		2	Methanol	32.755 mg.
		3	Methyl d-(-)-4-hydroxy-phenylglycinate OR D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]	502.40 mg.
		4	Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)	2.00 mg

	5	Potassium Clavulanate diluted with Microcrystalline Cellulose (1:1) / Clavulanate Potassium +Avicel [in Active Base]	303.773 mg
RA concerned may take further necessary action as per above decision of NC.			

Case No.	15 / NC/3/MEET/Oct/202324/15																
Case Status	Case Approved																
Party Name	AMI ORGANICS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023																
HQ File Number	HQRNORM REVIW00003496AM23																
RA File Number	522404000068 AM19																
Licence No and Date	5210042870/18/12/2018																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/May/202324/2 dated 12/05/2023 against advance authorization No. 5211002273 dated 30/03/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">4-HYDROXY COUMARIN (by Acetyl Salicylic Acid route)</td><td rowspan="2">1 kg.</td><td>1</td><td>Acetyl Salicylic Acid (For Industrial Use)</td><td>1.56 kg.</td></tr><tr><td>2</td><td>Ethyl Aceto Acetate</td><td>1.147 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	4-HYDROXY COUMARIN (by Acetyl Salicylic Acid route)	1 kg.	1	Acetyl Salicylic Acid (For Industrial Use)	1.56 kg.	2	Ethyl Aceto Acetate	1.147 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
4-HYDROXY COUMARIN (by Acetyl Salicylic Acid route)	1 kg.	1	Acetyl Salicylic Acid (For Industrial Use)	1.56 kg.													
		2	Ethyl Aceto Acetate	1.147 kg.													
RA concerned may take further necessary action as per above decision of NC																	

Case No.	16 / NC/3/MEET/Oct/202324/15			
Case Status	Case Deferred			
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM REVIW00004154AM23			
RA File Number	039404000526 AM20			
Licence No and Date	0310832396/23/10/2019			

Norms Committee Decision:

The firm was called for personal hearing for explanation of their case. The committee heard the explanation of the firm and after due deliberation the committee has directed to the firm to appear again before Norms Committee with all relevant documents, so that a decision could be taken.

Case No.	17 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	LACTOSE (INDIA) LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00002116AM23
RA File Number	039504001033 AM20
Licence No and Date	0310834414/23/01/2020

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.

Case No.	18 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	018205001136AM20
RA File Number	052404000749 AM20
Licence No and Date	0510413850/12/03/2020

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.
Buprenorphine Hydrochloride (Bulk Drug/ Pharmacopeal Grade)	1 kg.	1	7(Alpha)-(2-Hydroxy-3,3-Dimethyl-2-Butyl)-6, 14-Endo-Ethano-6, 7, 8, 14-Tetrahydronorthebaine	1.955 kg.
		2	Cyclopropyl methanol	1.60 kg.
		3	Mehtane Sulfonyl Chloride	2.50 kg.

		4	Lithium Bromide	2.00 kg.
		5	Thiophenol	2.50 kg.
		6	Dimethyl Formamide	4.00 kg.
		7	Triethyl Amine	4.80 kg.
		8	Toluene	20.50 kg.
		9	Methanol	5.50 kg.
		10	Activated Carbon / Eno Carbon	0.200 kg.
		11	Acetone	4.50 kg.

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

Case No.	19 / NC/3/MEET/Oct/202324/15			
Case Status	Case Approved			
Party Name	AMI ORGANICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM REVIW00003586AM23			
RA File Number	522404000007 AM21			
Licence No and Date	5210043401/22/05/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jul/202324/9 dated 28/07/2023 against advance authorization No. 5211002485 dated 13/05/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
5-NITROSO-2,4,6-TRIAMINOPYRIMIDINE	1 kg.	1	MALONONITRILE	0.571 kg.
		2	GUANIDINE HCL	0.826 kg.

		3	N,N DIMETHYL FORMAMIDE 99. 5% (Tech. Spec. Liquid)	0.632 kg.
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RA concerned may take further necessary action as per above decision of NC

Case No.	20 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	AMI LIFESCIENCES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00005662AM23
RA File Number	342404000171 AM21
Licence No and Date	3410046407/18/09/2020

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.
ESLICARBAZEPINE ACETATE	1 kg.	1	10-METHOXY IMINOSTILBENE	1.506 kg.

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

Case No.	21 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00000568AM23
RA File Number	052404000295 AM21
Licence No and Date	0510415273/21/09/2020

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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Meropenem for Injection	1 kg.	1	(4R, 5S, 6S)-3-[[(3S, 5S)-5-(Dimethylcarbamoyl)	0.8278 kg.
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RA concerned may take further necessary action as per above decision of NC

Case No.	22 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	AVA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00004365AM23
RA File Number	03AA04020902 AM21
Licence No and Date	0311001331/28/01/2021
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:- i. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. ii. Meaning of DTPA Ferric Sodium 13% with complete calculations based on chemistry of reaction.	

Case No.	23 / NC/3/MEET/Oct/202324/15	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023	
HQ File Number	HQRNORM REVIW00002205AM23	
RA File Number	03AA04021752 AM21	
Licence No and Date	0311001487/04/02/2021	
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	AMOXYCILLIN AND CLAVULANATE POTASSIUM TABLETS 625 MG ([The Relevant Bulk Drug content in the export product is Amoxcillin Trihydrate 40000 Kgs	1 Number

	and Clavulanate Potassium +Avicel 10000 KgA))	
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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.	24 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ORIENTAL AROMATICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00003798AM23
RA File Number	03AA04029725 AM21
Licence No and Date	0311002554/16/03/2021

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.
MYSORNAOL AB18019 (Perfumery Compound)	1 kg	1	Alpha Pinene	1.813 kg.
		2	Sec butanol	0.425 kg.

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

Case No.	25 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00002912AM23
RA File Number	05AA04041798 AM21
Licence No and Date	0511001982/01/04/2021

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.
Chloramphenicol Hemisuccinate (Anti Bacterial)	1 kg.	1	Chloramphenicol	1.16 kg.

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

Case No.	26 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00029824AM22
RA File Number	03AA04003827 AM22
Licence No and Date	0311003447/30/04/2021

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:-

Sl. No.	Export Product	Quantity
1	Medical Ointments/Creams(Clotrimazole 1 Percentage Cream 1/2 OZ 14 Gm Tube Total Net Wt. 500.01Kg, Cetostearyl Alcohol 50 Kg, Octyldodecanol 67.50Kg, Cetyl Esters 15 Kg, Sorbitan Mono 10 Kg, Polysorbate 60 NF 7.5 Kg, Clotrimazole USP 5.13 Kg, Benzyl Alcohol NF 5kg)	1 Number

2	Medical Ointments/Creams(Clotrimazole 1 Percentage Cream 1 OZ 28 Gm Tube Total Net Wt. 3300.02Kg, Cetostearyl Alcohol 330 Kg, Octyldodecanol 445.50Kg, Cetyl Esters 99 Kg, Sorbitan Mono 66 Kg, Polysorbate 60 NF 49.50 Kg, Clotrimazole USP 33.84Kg, Benzyl Alcohol NF 33 kg)	1 Number
3	Medical Ointments/Creams(Clotrimazole 1 Percentage Cream 45 Gm Tube with 1 Applicator Total Net Wt. 7219.49Kg, Cetostearyl Alcol 721.95Kg, Octyldo 974.63Kg, Cetyl Esters 216.58Kg, Sorbitan 144.39Kg, Polysorbate 108.29Kg, Clotri 74.04Kg, Benzyl 72.20Kg, Plas App 160433 Nos)	1 Number
4	Medical Ointments/Creams(Clotrimazole 1 Percentage Cream 45 Gm Tube with 7 Applicator Total Net Wt. 692.33Kg, Cetostearyl Alcol 69.23Kg, Octyldo 93.46Kg, Cetyl Esters 20.77Kg, Sorbitan 13.85Kg, Polysorbate 10.39Kg, Clotri 7.10Kg, Benzyl 6.92Kg, Plas App 15385 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.	27 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00001514AM23
RA File Number	03AA04011100 AM22
Licence No and Date	0311003600/06/05/2021
Norms Committee Decision: Shri Manuel Nazareth, GM and Shri Versing Shinde, Plant Head of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representatives of the firm and	

after personal hearing the committee has directed to the firm to appear again within one month before Norms Committee with all relevant documents, so that a decision could be taken.

Case No.	28 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00003538AM23
RA File Number	03AA04007907 AM22
Licence No and Date	0311003867/17/05/2021

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/Jan/202223/18 dated 23/01/2023** against advance authorization **No. 0310838453 dated 24/09/2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
COUMARIN	1 kg.	1	PHENOL	1.15 kg.
		2	XYLENE	0.50 kg.
		3	MAGNESIUM TURNINGS	0.148 kg.
		4	PARAFORMALDEHYDE	0.9177 kg.
		5	ACETIC ANHYDRIDE	0.7356 kg.

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

Case No.	29 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	U. K. AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00005651AM23
RA File Number	03AA04019445 AM22
Licence No and	0311004281/03/06/2021

Date				
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.
BENZYL PROPIONATE	1 kg.	1	PROPIONIC ACID	0.53 kg.
RA concerned may take further necessary action as per above decision of NC				

Case No.	30 / NC/3/MEET/Oct/202324/15			
Case Status	Case Approved			
Party Name	SAURAV CHEMICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM REVIW00002621AM23			
RA File Number	30AA04004647 AM22			
Licence No and Date	3011000736/12/06/2021			
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
KETOPROFEN	1 kg.	1	3 1 CYANOETHYL BENZOIC ACID	0.90 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	31 / NC/3/MEET/Oct/202324/15			
Case Status	Case Approved			
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM REVIW00004186AM23			
RA File Number	03AA04019330 AM22			
Licence No and Date	0311004745/19/06/2021			

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 FOR INJECTION (MEROPENEM BUFFERED STERILE) [Containing NLT 84% Sterile Meropenem]	1 kg.	1	MEROPENEM NON STERILE MEROPENEM TRIHYDRATE NON STERILE	0.8968 kg.
		2	Packing Material	Relevant, as per Packing Policy

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

Case No.	32 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	ORGANIC INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00129686AM22
RA File Number	06AA04003603 AM22
Licence No and Date	0611000533/02/07/2021

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to refer the case to **Norms Committee-6**.

Case No.	33 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00135125AM22
RA File Number	30AA04009718 AM22
Licence No and Date	3011000867/09/07/2021

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.
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VILDAGLIPTIN	1 Kg	1	L PROLINAMIDE	0.768 kg
		2	3 AMINO 1 ADAMANTANOL	0.769 kg
		3	IMIDAZOLE	0.464 kg
		4	METHYL ETHYL KETONE 2 BUTANONE	1.00 kg
		5	CYCLOHEXANE	0.50 kg
		6	POTASSIUM CARBONATE	0.74 kg
		7	ACETONE	0.80 kg

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

Case No.	34 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	VARTIKA CHEMICALS AND PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00002099AM23
RA File Number	NA
Licence No and Date	1311000462/22/07/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	35 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00148419AM22
RA File Number	31AA04021097 AM22
Licence No and Date	3111000476/27/07/2021
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:-

Copy of DML with complete composition of export items.

Case No.	36 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00150875AM22
RA File Number	05AA04055660 AM22
Licence No and Date	0511003910/30/07/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	37 / NC/3/MEET/Oct/202324/15			
Case Status	Case Approved			
Party Name	MEGHMANI NOVOTECH PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM APPLY 00160149AM22			
RA File Number	08AA04019584 AM22			
Licence No and Date	0811002298/11/08/2021			
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
BCMB (Bis Chloro Methyl Biphenyl)	1 kg	1	Biphenyl	1.389 kg.
		2	Paraformaldehyde	1.0 kg.
		3	Zinc Chloride Anhydrous	1.0 kg.
		4	Methanol	0.889 kg.

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

Case No.	38 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00165403AM22
RA File Number	05AA04062260 AM22
Licence No and Date	0511004178/18/08/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	39 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00003533AM23
RA File Number	03AA04055267 AM22
Licence No and Date	0311006418/25/08/2021

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:-

Sl. No.	Export Product	Quantity
1	Medical Creams/ Ointments(Clotrimazole 1 Percentage Cream 1/2 OZ 14 Gm Tube Tot Wt: 773.50 Kg (Net Cont: Ceto 77.35 Kg, Oct 104.42 Kg, Cetyl 23.21Kg, Sorbitan 15.47Kg, Polysorbate 11.60Kg, Clotrimazole 7.93 Kg, Benzyl 7.74Kg))	1 Number
2	Medical Creams/ Ointments(Clotrimazole 1 Percentage Cream 45 Gm Tube with 1 Applicator Tot Wt: 7120.31 Kg (Net Cont: Ceto 712.03 Kg, Oct 961.24Kg, Cetyl 213.61Kg, Sorbitan 142.41Kg, Polysorbate 106.80Kg, Clotrimazole 73.02 Kg, Benzyl 71.20Kg, App 158229 Nos))	1 Number
3	Medical Creams/ Ointments(Clotrimazole 1 Percentage Cream 45 Gm Tube with 7 Applicator Tot Wt: 791.19 Kg (Net Cont: Ceto 79.12 Kg, Oct 106.81Kg, Cetyl	Number

	23.74Kg, Sorbitan 15.82Kg, Polysorbate 11.87Kg, Clotrimazole 8.11 Kg, Benzyl 7.91Kg, App 17582 Nos))	
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.	40 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00177562AM22
RA File Number	08AA04023793 AM22
Licence No and Date	0811002515/06/09/2021

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.
OSELTAMIVIR PHOSPHATE FOR ORAL SUSPENSION 6MG/ML, 60ML((ACTIVE INGREDIENT: OSELTAMIVIR PHOSPHATE USP - NET WT. 1854.000 KGS.))	1 Number	1	OSELTAMIVIR PHOSPHATE USP	512.34 mg.
		2	NEOSORB P100T-SORBITOL	11162.16 mg
		3	XANTHAN GUM, XANTRUAL 180	195.00 mg.

		4	MONOSODIUM CITRATE D	695.00 mg.
		5	SODIUM SACCHARIN, DIHYDRATE, POWDER, USP	13.00 mg.
		6	ETHYL ALCOHOL 200 PROOF	1558.00 mg.
		7	TITANIUM DIOXIDE USP	195.00 mg.
		8	BOTTLE: AMBER GLASS 100 ML	Relevant as per Packing Policy
		9	CLOSURE: VISTOP CRC 28	Relevant as per Packing Policy

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

Case No.	41 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00181385AM22
RA File Number	08AA04024263 AM22
Licence No and Date	0811002550/10/09/2021

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.
Meropenem for injection 1 Gm (Each vial contains Meropenem 1000 mg on Anhydrous basis)	1 Vial	1	Meropenem with Sodium Carbonate USP	1.29 gm.

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

Case No.	42 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00192148AM22
RA File Number	03AA04091496 AM22
Licence No and Date	0311007180/23/09/2021
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:- i. Molar Weight of each input and output item of each stage. ii. Percentage yield on molar basis for each step. iii. CA certified Production/Consumption data. iv. 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.	43 / NC/3/MEET/Oct/202324/15	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023	
HQ File Number	HQRNORM APPLY 00195497AM22	
RA File Number	03AA040105795 AM22	
Licence No and Date	0311007265/27/09/2021	
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:-		
Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05 Percentage 15 Gm tube Tot Wt. 1500 Kgs (Net Cont: Clobetasol 0.78 Kg, Arlacel 67.50 Kgs, White Wax 15 Kgs, Empty Tubes: 100000 Nos))	1 Number
2	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05 Percentage 30 Gm tube Tot Wt. 2000.01Kgs (Net Cont: Clobetasol 1.04 Kg, Arlacel 90 Kgs, White Wax 20 Kgs, Empty Tubes: 66667 Nos))	1 Number

3	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05 Percentage 45 Gm tube Tot Wt. 1500.03Kgs (Net Cont: Clobetasol 0.78 Kg, Arlacel 67.50 Kgs, White Wax 15 Kgs, Empty Tubes: 33334 Nos))	Number
4	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05 Percentage 60 Gm tube Tot Wt. 2999.88Kgs (Net Cont: Clobetasol 1.56 Kg, Arlacel 135 Kgs, White Wax 30 Kgs, Empty Tubes: 49998 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.	44 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00197140AM22
RA File Number	09AA04015351 AM22
Licence No and Date	0911001652/29/09/2021

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.
VONOPRAZAN FUMARATE	1 kg.	1	5 -(2-fluorophenyl)-1H-pyrrole-3-carbaldehyde (FPC)	-0.757 kg.

		2	5-(2-Fluorophenyl)-1-(pyridin-3-ylsulfonyl)-1H-pyrrole-3-carbaldehyde. (VNF-I)	Not required.
		3	Pyridine-3-sulfonyl chloride	0.856 kg.

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

Case No.	45 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	KRITI NUTRIENTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00210670AM22
RA File Number	56AA04005794 AM22
Licence No and Date	5611000556/12/10/2021

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.
Soya Lecithin Liquid	1 MT	1	Crude Soya Lecithin	1.01 MT

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

Case No.	46 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	AMARA LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00211472AM22
RA File Number	09AA04016055 AM22
Licence No and Date	0911001711/13/10/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	47 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00001209AM23
RA File Number	08AA04033169 AM22
Licence No and Date	0811002929/20/10/2021

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.
MITOXANTRONE CONCENTRATE FOR SOLUTION FOR INFUSION 2MG/ML, 5ML VIAL(EACH ML CONTAINS: MITOXANTRONE HYDROCHLORIDE PH. EUR. EQ. TO MITOXANTRONE 2 MG)	1 Number	1	MITOXANTRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. (WATER + Residual Solvent NLT 3.56 %)	13.27 mg
MITOXANTRONE CONCENTRATE FOR SOLUTION FOR INFUSION 2MG/ML, 10 ML VIAL(EACH ML CONTAINS: MITOXANTRONE HYDROCHLORIDE PH. EUR. EQ. TO MITOXANTRONE 2 MG)	1 Number	2	MITOXANTRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. (WATER + Residual Solvent NLT 3.56 %)	26.54 mg
MITOXANTRONE CONCENTRATE FOR SOLUTION FOR INFUSION 2MG/ML, 15 ML VIAL(EACH ML CONTAINS: MITOXANTRONE HYDROCHLORIDE PH. EUR. EQ. TO MITOXANTRONE 2 MG [IN WHICH ACTIVE INGREDIENT MITOXANTRONE HCL USED IS 134.000 GRAMS])	1 Number	3	MITOXANTRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR. (WATER + Residual Solvent NLT 3.56 %)	38.01 mg

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

Case No.	48 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00220585AM22
RA File Number	05AA04090983 AM22
Licence No and Date	0511005557/21/10/2021
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. Stepwise complete and balanced chemical reaction with molar weight and percentage yields on molar basis for each step. 2. Past-Production-consumption data for three years.	

Case No.	49 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	BHAGWATI INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00219420AM22
RA File Number	08AA04033013 AM22
Licence No and Date	0811002934/21/10/2021
Norms Committee Decision: The case is under consideration for want of comments of TE	

Case No.	50 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00220583AM22
RA File Number	05AA04091027 AM22
Licence No and Date	0511005556/21/10/2021
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:- i. Stepwise complete and balanced chemical reaction with molar weight and percentage yields on molar basis for each step.	

ii. Past-Production-consumption data for three years.

Case No.	51 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00221594AM22
RA File Number	08AA04033661 AM22
Licence No and Date	0811002958/22/10/2021

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.
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 843.000 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.	52 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00227461AM22

RA File Number	03AA04097792 AM22			
Licence No and Date	0311007966/27/10/2021			
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.
TENOFIVIR DISOPROXIL FUMARATE	1 kg.	1	[(R)-9-(2-PHOSPHONYLMETHOXYPROPYL) ADENINE]	0.769 kg.
		2	MDC	1.363 kg.
		3	IPA	1.363 kg.
		4	CYCLOHEXANE	3.40 kg.
		5	N-METHYL-2-PYRROLIDONE?	1.4478 kg.
		6	CHLOROMETHYL ISOPROPYL CARBONATE	1.3527 kg.

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

Case No.	53 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00006964AM23
RA File Number	09AA04016788 AM22
Licence No and Date	0911001796/29/10/2021
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.
Calcium and Colecalciferol Tablets 500mg/400 IU(D-CALSOR 500mg/400 IU)(Calcium and Colecalciferol Tablets 500mg/400 IU(D-CALSOR 500mg/400 IU))	1 Number	1	Colecalciferol concentrate (powder form)] (Dry Vitamin D3 100 SD/S)	4.73 mg
Calcium and Colecalciferol Tablets 500mg/800 IU(D-CALSOR 500mg/800 IU)(Calcium and Colecalciferol Tablets 500mg/800 IU(D-CALSOR 500mg/800 IU))	1 Number	2	Colecalciferol concentrate (powder form)] (Dry Vitamin D3 100 SD/S)	9.56 mg

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

Case No.	54 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00239769AM22
RA File Number	09AA04001389 AM22
Licence No and Date	0911001808/02/11/2021
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.	55 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00003766AM23
RA File Number	03AA040116810 AM22
Licence No and Date	0311008170/02/11/2021
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.
2,5-DIMERCAPTO-1,3,4-THIADIAZOLE(YALUB DMTD)	1 kg.	1	HYDRAZINE HYDRATE (Max. 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.	56 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00253270AM22
RA File Number	05AA04099135 AM22
Licence No and Date	0511006147/15/11/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	57 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00255868AM22
RA File Number	03AA040112749 AM22
Licence No and Date	0311008637/17/11/2021
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.	

Case No.	58 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00255297AM22
RA File Number	34AA04009240 AM22
Licence No and Date	3411001409/17/11/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	59 / NC/3/MEET/Oct/202324/15			
Case Status	Case Approved			
Party Name	FRESENIUS KABI ONCOLOGY LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM APPLY 00262432AM22			
RA File Number	05AA04098038 AM22			
Licence No and Date	0511006369/23/11/2021			
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/Nov/202223/12 dated 18/11/2022 against advance authorization No.0511011349 dated 24/03/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Gemcitabine Hydrochloride USP	1 gram	1	2-Deoxy-2,-difluoro-D-ribofuranose-3,5-dibenzoate-1-methanesulphonate (T-8).	5.40 gram
		2	N Acetylcytosine	2.92 gram
RA concerned may take further necessary action as per above decision of NC.				

Case No.	60 / NC/3/MEET/Oct/202324/15			
Case Status	Case Approved			
Party Name	INTAS PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM APPLY 00266181AM22			
RA File Number	08AA04035102 AM22			
Licence No and Date	0811003242/26/11/2021			

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/Aug/202324/11 dated 22/08/2023** against advance authorization **No.0811002696 dated 27/09/2021**, 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.
TOPOTECAN INJECTION 1 MG/ML, 1 ML VIAL (EACH ML CONTAINS TOPOTECAN HYDROCHLORIDE EQ. TO TOPOTECAN 1MG)	1 Number	1	TOPOTECAN HYDROCHLORIDE (Water and Residual solvents content not less than 9.0% in the API)	1.313 mg.
TOPOTECAN INJECTION 1 MG/ML, 4 ML VIAL (EACH ML CONTAINS TOPOTECAN HYDROCHLORIDE EQ. TO TOPOTECAN 1 MG)	1 Number	2	TOPOTECAN HYDROCHLORIDE (Water and Residual solvents content not less than 9.0% in the API)	5.16 mg.
TOPOTECAN HYDROCHLORIDE FOR INJECTION 4MG/VIAL (5ML VIAL) (EACH VIAL CONTAINS TOPOTECAN HYDROCHLORIDE EQ. TO TOPOTECAN 4 MG [IN WHICH ACTIVE INGREDIENT TOPOTECAN HYDROCHLORIDE USED IS 71.000 GRAMS])	1 Number	3	TOPOTECAN HYDROCHLORIDE (Water and Residual solvents content not less than 9.0% in the API)	5.16 mg.

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

Case No.	61 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00276162AM22
RA File Number	03AA040123869 AM22
Licence No and Date	0311009212/06/12/2021

Norms Committee Decision:

Shri Manuel Nazareth, GM and Shri Versing Shinde, Plant Head of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representatives of the firm and after personal hearing the committee has directed to the firm to appear again within one month before

Norms Committee with all relevant documents, so that a decision could be taken.

Case No.	62 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00283764AM22
RA File Number	09AA04017426 AM22
Licence No and Date	0911001978/13/12/2021

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.
1-[(3R,4S)-4-Cyanotetrahydropyran-3-yl]-3-[(2-fluoro-6-methoxy-4-pyridyl)amino]pyrazole-4-carboxamide((L-005251026-Form-I))	1 kg.	1	Ethyl-3-amino-1-4-cyanotetrahydro-2H-pyran-3-yl)-1H-Pyrazole-4-carboxylate (Racemic ECPC)	5.120 kg.
		2	2-Fluoro-4-Iodo-6-Methoxy Pyridine (IFMP)	2.267 kg.
		3	4,5-bis(Diphenylphosphino)-9,9-dimethylxanthane (Xantphos)	0.153 kg.

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

Case No.	63 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM REVIW00006199AM23
RA File Number	09AX04000002 AM22
Licence No and Date	0911002041/13/12/2021

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.
AMOXYCILLIN AND CLAVULANATE POTASSIUM TABLETS 1000 MG (each film coated Tablet contains: amoxicillin Trihydrate Equivalent to Amoxicillin 875 mg, Clavulanate Potassium equivalent to Clavulanic Acid 125 mg.	1 Number	1	6-Amino penicillanic acid (6-APA)	581.77 mg.
		2	D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]	502.40 mg.
		3	Penicillin G Amidase	2.00 mg.
		4	Diluted Clavulanate Potassium (1:1) / Potassium Clavulanate Diluted with Microcrystalline Cellulose (1:1)	303.773 mg.

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

Case No.	64 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00285202AM22
RA File Number	09AA04017427 AM22
Licence No and Date	0911002053/14/12/2021

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.
1-[(3R,4S)-4-Cyanotetrahydropyran-3-yl]-3-[(2-fluoro-6-methoxy-4-pyridyl)amino]pyrazole-4-carboxamide ((L-005251026-Form-I))	1 kg.	1	4,5-bis(Diphenylphosphino)-9,9-dimethylxanthane (Xantphos)	0.153 kg.
		2	Ethyl-3-amino-1-4-cyanotetrahydro-2H-pyran-3-yl)-1H-Pyrazole-4-carboxylate (Racemic ECPC)	5.120 kg.

		3	2-Fluoro-4-Iodo-6-Methoxy Pyridine (IFMP)	2.267 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	65 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00287478AM22
RA File Number	03AA040122138 AM22
Licence No and Date	0311009510/16/12/2021
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.	

Case No.	66 / NC/3/MEET/Oct/202324/15			
Case Status	Case Approved			
Party Name	INFICHEM PHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM APPLY 00291201AM22			
RA File Number	52AX04000002 AM22			
Licence No and Date	5211001739/20/12/2021			
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.
2,7-DICHLORO-9H-FLUORENE (DCF)	1 kg.	1	FLUORENE	1.18 kg.
		2	DIMETHYL FORMAMIDE (DMF)	1.10 kg.

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

Case No.	67 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00291474AM22
RA File Number	08AX04000083 AM22
Licence No and Date	0811003487/20/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jan/202223/18 dated 23/01/2023** against advance authorization **No. 0811001969 dated 12/07/2021** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Q PARIN 1000 IU/ML (HEPARIN SODIUM INJECTION USP/BP 5000 IU)	1 Number	1	HEPARIN SODIUM BP (580 MEGA) (Potency 156.3 IU/mg)	175.944 mg.
Q PARIN 5000 IU/ML (HEPARIN SODIUM INJECTION USP/BP 25000 IU)	1 Number	2	HEPARIN SODIUM BP (580 MEGA) (Potency 156.3 IU/mg)	35.189 mg

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

Case No.	68 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00291533AM22
RA File Number	34AX04000052 AM22
Licence No and Date	3411001560/20/12/2021
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.
Temazepam Caps Usp 7.5 mg (Temazepam Caps Usp 7.5 mg (net content of active ingredients = 22.50 kgs))	1 Number	1	Temazepam USP	7.65 mg
		2	Lactose monohydrate (Spherolac 100)	169.13 mg
		3	Croscarmellose Sodium (Ac-Di-Sol)	6.90 mg
		4	Microcrystalline Cellulose (Avicel PH200)	42.47 mg
		5	Sodium Lauryl Sulfate	2.00 mg
		6	Magnesium Stearate	2.00 mg
Temazepam Caps Usp 15 mg (Temazepam Caps Usp 15 mg (net content of active ingredients = 135.00 kgs))	1 Number	7	Temazepam USP	15.30 mg
		8	Lactose monohydrate (Spherolac 100)	161.63 mg
		9	Croscarmellose Sodium (Ac-Di-Sol)	6.90 mg
		10	Microcrystalline Cellulose (Avicel PH200)	42.47 mg
		11	Sodium Lauryl Sulfate	2.00 mg
		12	Magnesium Stearate	2.00 mg
Temazepam Caps Usp 22.5 mg (Temazepam Caps Usp 22.5 mg (net content of active ingredients = 67.500 kgs))	1 Number	13	Temazepam USP	22.95 mg
		14	Lactose monohydrate (Spherolac 100)	154.13 mg
		15	Croscarmellose Sodium (Ac-Di-Sol)	6.90 mg
		16	Microcrystalline Cellulose (Avicel PH200)	42.47 mg

		17	Sodium Lauryl Sulfate	2.00 mg
		18	Magnesium Stearate	2.00 mg
Temazepam Caps Usp 30 mg (Temazepam Caps Usp 30 mg (net content of active ingredients = 270.00 kgs))	1 Number	19	Temazepam USP	30.60 mg
		20	Lactose monohydrate (Spherolac 100)	146.63 mg
		21	Croscarmellose Sodium (Ac-Di-Sol)	6.90 mg
		22	Microcrystalline Cellulose (Avicel PH200)	42.47 mg
		23	Sodium Lauryl Sulfate	2.00 mg
		24	Magnesium Stearate	2.00 mg

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

Case No.	69 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00298292AM22
RA File Number	08AX04000091 AM22
Licence No and Date	0811003537/27/12/2021

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.
BUSPIRONE HYDROCHLORIDE TABLETS USP 5 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 5 MG)	29000000 Numbers	1	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	147.90 kg

BUSPIRONE HYDROCHLORIDE TABLETS USP 7.5 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 7.5 MG)	15000000 Numbers	2	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	114.75 kg
BUSPIRONE HYDROCHLORIDE TABLETS USP 10 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 10 MG)	8000000 Numbers	3	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	81.60 kg
BUSPIRONE HYDROCHLORIDE TABLETS USP 15 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 15 MG)	5000000 Numbers	4	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	76.50 kg
BUSPIRONE HYDROCHLORIDE TABLETS USP 30 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 30 MG [IN WHICH ACTIVE INGREDIENT BUSPIRONE HYDROCHLORIDE USED IS 484.500 KGS.]	2400000 Numbers	5	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	73.44 kg

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

Case No.	70 / NC/3/MEET/Oct/202324/15			
Case Status	Case Approved			
Party Name	AUROBINDO PHARMA LTD			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM REVIW00006967AM23			
RA File Number	09AX04000070 AM22			
Licence No and Date	0911002189/28/12/2021			
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.
Calcium and Colecalciferol Tablets 500mg/400 IU(D-CALSOR 500mg/400 IU)(Calcium and Colecalciferol Tablets	1 Number	1	Colecalciferol concentrate (powder form)] (Dry Vitamin D3 100 SD/S)	4.73 mg

500mg/400 IU(D-CALSOR 500mg/400 IU))				
Calcium and Colecalciferol Tablets 500mg/800 IU(D-CALSOR 500mg/800 IU)(Calcium and Colecalciferol Tablets 500mg/800 IU(D-CALSOR 500mg/800 IU))	1 Number	2	Colecalciferol concentrate (powder form)] (Dry Vitamin D3 100 SD/S)	9.56 mg

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

Case No.	71 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00299344AM22
RA File Number	07AA04038998 AM22
Licence No and Date	0711002737/28/12/2021
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was observed that the firm has still not furnished the following documents/information. Therefore, the committee decided to call for the same from the firm:- 1. Complete chemical reactions with molecular and structural formula and molecular weights alongwith stage wise percentage yields on molar basis. 2. 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.	72 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00310736AM22
RA File Number	05AX04000472 AM22
Licence No and Date	0511007713/07/01/2022
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. **Stepwise complete and balanced chemical reaction with molar weight and percentage yields on molar basis for each step.**
- ii. **Past-Production-consumption data for three years**

Case No.	73 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00310737AM22
RA File Number	05AX04000473 AM22
Licence No and Date	0511007715/07/01/2022

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. **Stepwise complete and balanced chemical reaction with molar weight and percentage yields on molar basis for each step.**
- ii. **Past-Production-consumption data for three years.**

Case No.	74 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00317040AM22
RA File Number	08AX04000199 AM22
Licence No and Date	0811003776/13/01/2022

Norms Committee Decision:

The Committee considered the case as per agenda and observed that the Master Batch Formula for export item 1 to 4 are not given separately and details given so far are confusing, therefore, it was decided to call the firm for attending **Personal Hearing** before Norms Committee to explain its case.

Case No.	75 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD

Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00326841AM22
RA File Number	09AA04016329 AM22
Licence No and Date	0911002348/21/01/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	76 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00329136AM22
RA File Number	03AX04000717 AM22
Licence No and Date	0311010813/24/01/2022

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:-

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Bacitracin Zinc Ointment 0.5 OZ /14 GM Tube Tot Wt: 399Kgs (Net Cont: Bacitracin 3.38 Kgs))	1 Number
2	Medical Creams & Ointments(Bacitracin Zinc Ointment 1 OZ / 28 GM Tube Tot Wt: 5598.79Kgs (Net Cont: Bacitracin 47.37Kgs))	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: 1604.26Kgs (Net Cont: Bacitracin 13.57Kgs, Polymixin 2.94Kgs))	1 Number
5	Medical Creams & Ointments(Triple Antibiotic Ointment W/ Pramoxine HCL 0.2 OZ / 14 GM Tube Tot Wt: 2918.86Kgs (Net Cont: Baci 24.69Kgs, Poly 5.34Kgs, Neo 20.43Kgs, Pramo 29.77Kgs))	1 Number
6	Medical Creams & Ointments(Triple Antibiotic Ointment 1 OZ / 28 Gm Tube Tot Wt: 1641Kgs (Net Cont: Baci 10.51Kgs, Poly 1.39Kgs, Neo 11.48Kgs))	1 Number
7	Medical Creams & Ointments(Triple MS Antibiotic Ointment 1 OZ / 28 Gm Tube Tot Wt: 1090.04Kgs (Net Cont: Baci 9.22Kgs, Poly 2Kgs, Neo 7.63Kgs))	1 Number

8	Medical Creams & Ointments(Triple MS Antibiotic Ointment 0.5 OZ / 14 Gm Tube Tot Wt: 518Kgs (Net Cont: Baci 4.38Kgs, Poly 0.95Kgs, Neo 3.62Kgs))	1 Number
9	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
10	Medical Creams & Ointments(Triple Antibiotic Ointment W/ Pramoxine HCL 1 OZ / 28 GM Tube Tot Wt: 448Kgs (Net Cont: Baci 3.79Kgs, Poly 0.82Kgs, Neo 3.14Kgs, Pramo 4.57Kgs))	1 Number
11	Medical Creams & Ointments(Triple Antibiotic Ointment W/ Pramoxine HCL 2 OZ / 56 GM Tube Tot Wt: 10286.19Kgs (Net Cont: Baci 87.02Kgs, Poly 18.82Kgs, Neo 71.98Kgs, Pramo 104.92Kgs))	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.	77 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00331260AM22
RA File Number	03AX04000915 AM22
Licence No and Date	0311010867/25/01/2022

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:-

Sl. No.	Export Product	Quantity
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1	Medical Creams & Ointments(FLUOCINONIDE TOPICAL SOLUTION 0.05% 60 ML Tot Wt: 8675.80Kgs (Net Cont: Fluocin 4.75Kgs, Ethyl 2601.08Kgs, Iso 563.93Kgs, Bottle 152207Nos, Cap 152207Nos, Needle 152207Nos))	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.	78 / NC/3/MEET/Oct/202324/15													
Case Status	Case Approved													
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023													
HQ File Number	HQRNORM APPLY 00332964AM22													
RA File Number	09AX04000151 AM22													
Licence No and Date	0911002396/27/01/2022													
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="2">1-[(3R,4S)-4-Cyanotetrahydropyran-3-yl]-3-[(2-fluoro-6-methoxy-4-pyridyl) amino]pyrazole-4-carboxamide ((L- 005251026-Form-I))</td><td rowspan="2">1 kg</td><td>1</td><td>2-Fluoro-6-methoxy pyridine (FMP)</td><td>3.23 kg.</td></tr><tr><td>2</td><td>4,5-bis(Diphenylphosphino)-9,9-dimethylxanthane (Xantphos)</td><td>0.153 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	1-[(3R,4S)-4-Cyanotetrahydropyran-3-yl]-3-[(2-fluoro-6-methoxy-4-pyridyl) amino]pyrazole-4-carboxamide ((L- 005251026-Form-I))	1 kg	1	2-Fluoro-6-methoxy pyridine (FMP)	3.23 kg.	2	4,5-bis(Diphenylphosphino)-9,9-dimethylxanthane (Xantphos)	0.153 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed										
1-[(3R,4S)-4-Cyanotetrahydropyran-3-yl]-3-[(2-fluoro-6-methoxy-4-pyridyl) amino]pyrazole-4-carboxamide ((L- 005251026-Form-I))	1 kg	1	2-Fluoro-6-methoxy pyridine (FMP)	3.23 kg.										
		2	4,5-bis(Diphenylphosphino)-9,9-dimethylxanthane (Xantphos)	0.153 kg.										

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

Case No.	79 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00343395AM22
RA File Number	03AX04001061 AM22
Licence No and Date	0311011086/04/02/2022

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.
PDSH (PDSH Technical)	1 kg.	1	2 FLURO ANILINE	0.66 kg.
		2	ETHYL CHLOROFORMATE	0.55 kg.
		3	DI METHYL FORMAMIDE	Deleted (not given in production/consumption data and also not a main reactant)

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

Case No.	80 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00346268AM22
RA File Number	34AX04000204 AM22
Licence No and Date	3411001767/07/02/2022

Norms Committee Decision:

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

Case No.	81 / NC/3/MEET/Oct/202324/15
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Case Status	Case Approved
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00347306AM22
RA File Number	08AX04000205 AM22
Licence No and Date	0811003993/08/02/2022

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.
Phenylephrine Hydrochloride Injection USP, 10 mg/mL (1 mL) (Phenylephrine Hydrochloride Injection USP, 10 mg/mL (1 mL))	1 Number	1	PHENYLEPHRINEHYDROCHLORIDE USP SIEGFRIED	11.00 mg.
Phenylephrine Hydrochloride Injection USP, 10 mg/mL (5 mL) (Phenylephrine Hydrochloride Injection USP, 10 mg/mL (5 mL))	1 Number	2	PHENYLEPHRINEHYDROCHLORIDE USP SIEGFRIED	55.00 mg.
Phenylephrine Hydrochloride Injection USP, 10 mg/mL (10 mL) (Phenylephrine Hydrochloride Injection USP, 10 mg/mL (10 mL))	1 Number	3	PHENYLEPHRINEHYDROCHLORIDE USP SIEGFRIED	110.00 mg.

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

Case No.	82 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00348248AM22
RA File Number	03AX04001105 AM22
Licence No and Date	0311011230/09/02/2022

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:-

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(CLINDAMYCIN PHOSPHATE TOP. LOT. 1% 60ML Tot Wt: 24600Kgs (Net Cont: Stearic 516.61 Kgs, Kolliwax 645.76 Kgs, Clindamycin 306.87 Kgs, Bottle 430500 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.	83 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00350237AM22
RA File Number	05AX04000943 AM22
Licence No and Date	0511008753/10/02/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	84 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023

HQ File Number	HQRNORM APPLY 00355981AM22
RA File Number	03AX04001160 AM22
Licence No and Date	0311011415/15/02/2022

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:-

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Clobetasol Propionate Ointment 0.05% 15Gm Tot Wt: 2999.97 Kgs (Net Cont Clobetasol 1.55Kgs, Sorbitan 15Kgs, White Petrolatum 2833.47Kgs, Tubes 199998Nos))	1 Number
2	Medical Creams & Ointments(Clobetasol Propionate Ointment 0.05% 30Gm Tot Wt: 999.96 Kgs (Net Cont Clobetasol 0.52Kgs, Sorbitan 5Kgs, White Petrolatum 944.46Kgs, Tubes 33332Nos))	1 Number
3	Medical Creams & Ointments(Clobetasol Propionate Ointment 0.05% 45Gm Tot Wt: 500Kgs (Net Cont Clobetasol 0.26Kgs, Sorbitan 2.50Kgs, White Petrolatum 472.25Kgs, Tubes 11111Nos))	1 Number
4	Medical Creams & Ointments(Clobetasol Propionate Ointment 0.05% 60Gm Tot Wt: 18499.74Kgs (Net Cont Clobetasol 9.58Kgs, Sorbitan 92.50Kgs, White Petrolatum 17473Kgs, Tubes 308329Nos))	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.	85 / NC/3/MEET/Oct/202324/15
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Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00355978AM22
RA File Number	03AX04001161 AM22
Licence No and Date	0311011414/15/02/2022

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:-

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05% 15 Gm tube Tot Wt: 1750.01Kgs (Net Cont: Clob 0.98 Kgs, Arlacel 85.50Kgs, White Wax 18.90Kgs, Tubes 126000 Nos))	1 Number
2	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05% 30 Gm tube Tot Wt: 5000.10 Kgs (Net Cont: Clob 2.80Kgs, Arlacel 243.01Kgs, White Wax 54Kgs, Tubes 180004Nos))	1 Number
3	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05% 45 Gm tube Tot Wt: 4250.16 Kgs (Net Cont: Clob 2.38Kgs, Arlacel 206.56Kgs, White Wax 45.90Kgs, Tubes 102004Nos))	1 Number
4	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05% 60 Gm tube Tot Wt: 7499.70 Kgs (Net Cont: Clob 4.20Kgs, Arlacel 364.49Kgs, White Wax 81Kgs, Tubes 134995Nos))	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.	86 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00356333AM22
RA File Number	08AX04000425 AM22
Licence No and Date	0811004071/15/02/2022

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.
BUSPIRONE HYDROCHLORIDE TABLETS USP 5 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 5 MG)	29000000 Numbers	1	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	147.90 kg
BUSPIRONE HYDROCHLORIDE TABLETS USP 7.5 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 7.5 MG)	15000000 Numbers	2	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	114.75 kg
BUSPIRONE HYDROCHLORIDE TABLETS USP 10 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 10 MG)	8000000 Numbers	3	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	81.60 kg
BUSPIRONE HYDROCHLORIDE TABLETS USP 15 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 15 MG)	5000000 Numbers	4	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	76.50 kg
BUSPIRONE HYDROCHLORIDE TABLETS USP 30 MG (EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 30 MG [IN WHICH ACTIVE INGREDIENT	2400000 Numbers	5	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	73.44 kg

BUSPIRONE HYDROCHLORIDE USED IS 484.500 KGS.)				
RA concerned may take further necessary action as per above decision of NC				

Case No.	87 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	GANGWAL HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00356909AM22
RA File Number	03AX04001205 AM22
Licence No and Date	0311011422/16/02/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	88 / NC/3/MEET/Oct/202324/15			
Case Status	Case Approved			
Party Name	MEGHMANI NOVOTECH PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM APPLY 00357589AM22			
RA File Number	08AX04000262 AM22			
Licence No and Date	0811004084/16/02/2022			
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
BCMB (Bis Chloro Methyl Biphenyl)	1 kg	1	Biphenyl	1.389 kg.
		2	Paraformaldehyde	1.0 kg.
		3	Zinc Chloride Anhydrous	1.0 kg.
		4	Methanol	0.889 kg.

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

Case No.	89 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00359473AM22
RA File Number	03AX04001229 AM22
Licence No and Date	0311011469/18/02/2022

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:-

Sl. No.	Export Product	Quantity
1	Medical Creams & Ointments(Clotrimazole 1 % Cream 1/2 OZ 14 Gm Tube Tot Wt: 735Kgs (Net Cont: Ceto 73.50Kgs, Octy 99.23Kgs, Cetyl 22.05Kgs, Sorb 14.70Kgs, Poly 11.03Kgs, Clotri 7.54Kgs, Benzyl 7.35Kgs))	1 Number
2	Medical Creams & Ointments (Clotrimazole 1 % Cream 1 OZ 28 Gm Tube Tot Wt: 3263.40Kgs (Net Cont: Ceto 326.34Kgs, Octy 440.56Kgs, Cetyl 97.90Kgs, Sorb 65.27Kgs, Poly 48.95Kgs, Clotri 33.47Kgs, Benzyl 32.63Kgs))	1 Number
3	Medical Creams & Ointments(Clotrimazole 1 % Cream 45 Gm Tube with 1 Applicator Tot Wt: 17800.56Kgs (Net Cont: Ceto 1780.06Kgs, Octy 2403.08Kgs, Cetyl 534.02Kgs, Sorb 356.01Kgs, Poly 267.01Kgs, Clotri 182.55Kgs, Benzyl 178.01Kgs, App 395568 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.	90 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00359728AM22
RA File Number	08AX04000474 AM22
Licence No and Date	0811004112/18/02/2022

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/202223/5 dated 08/07/2022** against advance authorization **No.0811000632 dated 10/02/2021**, 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.
HEPARIN INJECTION 25000IU	123360 Vials	1	HEPARIN SODIUM IP 2018 EP Mega 3378.89	15.21 kg.
HEPARIN INJECTION 5000IU	305316 Vials	2	HEPARIN SODIUM IP 2018 EP Mega 1671.11	7.52 kg.

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

Case No.	91 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00359783AM22
RA File Number	34AX04000191 AM22
Licence No and Date	3411001829/18/02/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
3-HYDROXY BENZOTRIFLUORIDE (MHBTF)	1 kg.	1	BENZOTRIFLUORIDE	1.022 kg.
		2	TOLUENE	0.28 kg.

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

Case No.	92 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00367536AM22
RA File Number	08AX04000483 AM22
Licence No and Date	0811004214/25/02/2022

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.0811002696 dated 27/09/2021**, 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.
TOPOTECAN INJECTION 1 MG/ML, 1 ML VIAL(EACH ML CONTAINS TOPOTECAN HYDROCHLORIDE EQ. TO TOPOTECAN 1MG)	1 Number	1	TOPOTECAN HYDROCHLORIDE (Water and Residual solvents content not less than 9.0% in the API)	1.313 mg
TOPOTECAN INJECTION 1 MG/ML, 4 ML VIAL(EACH ML CONTAINS TOPOTECAN HYDROCHLORIDE EQ. TO TOPOTECAN 1 MG)	1 Number	2	TOPOTECAN HYDROCHLORIDE (Water and Residual solvents content not less than 9.0% in the API)	5.16 mg
TOPOTECAN HYDROCHLORIDE FOR INJECTION 4MG/VIAL (5ML VIAL)(EACH VIAL CONTAINS TOPOTECAN HYDROCHLORIDE EQ. TO TOPOTECAN 4 MG [IN WHICH ACTIVE INGREDIENT TOPOTECAN HYDROCHLORIDE USED IS 71.000	1 Number	3	TOPOTECAN HYDROCHLORIDE (Water and Residual solvents content not less than 9.0% in the API)	5.16 mg

GRAMS))

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

Case No.	93 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00367541AM22
RA File Number	08AX04000478 AM22
Licence No and Date	0811004216/25/02/2022

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.	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.	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.	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
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.	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.	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.	5737.00 mg/vial
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RA concerned may take further necessary action as per above decision of NC.

Case No.	94 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00367543AM22
RA File Number	08AX04000490 AM22
Licence No and Date	0811004217/25/02/2022

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.
BUSPIRONE HYDROCHLORIDE TABLETS USP 5 MG(EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 5 MG)	1 Number	1	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	5.10 mg
BUSPIRONE HYDROCHLORIDE TABLETS USP 7.5 MG(EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 7.5 MG)	1 Number	2	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	7.65 mg
BUSPIRONE HYDROCHLORIDE TABLETS USP 10 MG(EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 10 MG)	1 Number	3	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	10.20 mg
BUSPIRONE HYDROCHLORIDE TABLETS USP 15 MG(EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 15 MG)	1 Number	4	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	15.30 mg

BUSPIRONE HYDROCHLORIDE TABLETS USP 30 MG(EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 30 MG [IN WHICH ACTIVE INGREDIENT BUSPIRONE HYDROCHLORIDE USED IS 637.500 KGS.]	1 Number	5	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	30.60 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	95 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00371441AM22
RA File Number	09AX04000232 AM22
Licence No and Date	0911002575/01/03/2022
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:-	
1. Complete Technical details as per Appendix-4E. 2. Material balance, showing solvents recovery.	

Case No.	96 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	VIVIMED LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00378088AM22
RA File Number	04AX04000278 AM22
Licence No and Date	0411002806/07/03/2022
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. 2/82-ALC4/2020 dated 10/07/2020 against advance authorization No. 0910068240 dated 02/12/2019 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ibuprofen Tablets USP - 800mg	1 Number Tablet	1	Ibuprofen	816 mg.
		2	Pregelatinized Starch	34.75 mg.
		3	Sodium Starch Glycolate	46.00 mg
		4	Mg Stearate - Veg Source (Magnesium Stearate)	5.75 mg.

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

Case No.	97 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00380949AM22
RA File Number	34AX04000157 AM22
Licence No and Date	3411001935/09/03/2022
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.	

Case No.	98 / NC/3/MEET/Oct/202324/15
Case Status	Case Approved
Party Name	SHIVA BIO CHEM INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00382075AM22
RA File Number	50AX04000031 AM22
Licence No and Date	5011000413/10/03/2022
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.
Sunflower Lecithin Powder	1 MT	1	Sunflower Lecithin Liquid	1.40 MT

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

Case No.	99 / NC/3/MEET/Oct/202324/15			
Case Status	Case Approved			
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023			
HQ File Number	HQRNORM APPLY 00386436AM22			
RA File Number	03AX04001649 AM22			
Licence No and Date	0311012801/14/03/2022			
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.
Sodium Lactate (Hartmann's) Solution for injection, 1000ml	1 Number	1	SODIUM LACTATE (PURASAL SP/F 50)(EP) (Sodium Lactate 50% Solution)	6.657 gm

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

Case No.	100 / NC/3/MEET/Oct/202324/15
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Oct/ 202324/ 15 and 13/10/2023
HQ File Number	HQRNORM APPLY 00386056AM22
RA File Number	08AX04000650 AM22
Licence No and Date	0811004377/14/03/2022
Norms Committee Decision:	

The case is under consideration for want of comments of TE