



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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III**MEETING No.** NC/3/MEET/Jun/202425/5**DATED:** 14/06/2024Please Note

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

Meeting No. NC/3/MEET/Jun/202425/5 dated 14/06/2024 of Norms Committee - III for the year 2024-25 was held on 14/06/2024 under the Chairmanship of Shri Rakesh Kumar, Additional DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2023.

The following members were present in the meeting:-

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

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

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Jun/202425/5			
Case Status	Case Approved			
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024			
HQ File Number	HQRNORM APPLY 00008586AM24			
RA File Number	NA			
Licence No and Date	NA			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-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.
SULFADOXINE	1 kg.	1	4,6 Dichloro 5-Methoxy Pyrimidine (DCMP)	0.78 kg.
		2	SULFANILAMIDE	0.90 kg.
		3	Diethyl oxalate	Not shown in process.
		4	DIMETHYL FORMAMIDE (DMF)	1.00 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	2 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00008231AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	

The Committee considered the case as per agenda and it was decided to fix ad-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.
SULFADOXINE	1 kg.	1	4,6 Dichloro 5-Methoxy Pyrimidine (DCMP)	0.78 kg.
		2	SULFANILAMIDE	0.90 kg.
		3	Diethyl oxalate	Not shown in process.

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

Case No.	3 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00007891AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The case is under consideration for want of comments of Deptt. of Bio-Technology. Reminder issued.	

Case No.	4 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	GREEN PINE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024

HQ File Number	HQRNORM APPLY 00006239AM24													
RA File Number	NA													
Licence No and Date	NA													
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="197 603 1428 798"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>BETA PINENE</td> <td>1 kg.</td> <td>1</td> <td>Gum Turpentine oil</td> <td>1.15 kg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	BETA PINENE	1 kg.	1	Gum Turpentine oil	1.15 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
BETA PINENE	1 kg.	1	Gum Turpentine oil	1.15 kg.										

Case No.	5 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00004206AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was observed that during the Personal Hearing held on 16/05/2024, the firm was advised to furnish the following information/documents, however, the same still not received from the firm. Therefore, it was decided that the firm may be again advised to furnish the following documents as sought earlier: Complete batch chemical reaction showing description of export and import item along with percentage yield on molar basis. Certificate of Analysis (CoA) of import item to explain the complete description of import item No.1	

Case No.	6 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	SATYAJIT CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00005534AM24
RA File Number	NA
Licence No and Date	0310786462/07/07/2014

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.2/82-ALC4/2018 dated 16/05/2018** against advance authorization **No.0310811095 dated 09/02/2017**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
EDTA Ferric Sodium [EDTA Fe]	1 kg.	1	Ethylene Diamine Tetra Acetic Acid (EDTA)	0.730 kg.

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

Case No.	7 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00007896AM24
RA File Number	072404000347 AM16
Licence No and Date	0710109255/12/01/2016
Norms Committee Decision:	

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

1. **Content of API is not mentioned in export item No. 2 and 3.**
2. **No Drug Manufacturing Licence (DML) given for export item No. 12.**
3. **Certificate of Analysis (CoA) for import item No.1 is not given in support of its specification.**
4. **Description of import item No. 2 and 3 not matching with CoA of actual import.**

Case No.	8 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00007908AM24
RA File Number	072404000160 AM17
Licence No and Date	0710110226/08/08/2016
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	9 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00007894AM24
RA File Number	072404000182 AM17
Licence No and Date	0710110335/30/08/2016
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	10 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000261AM24
RA File Number	039404000617 AM17
Licence No and Date	0310808312/06/10/2016
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	11 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00007903AM24
RA File Number	072404000273 AM17
Licence No and Date	0710110770/09/12/2016
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	12 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00007898AM24
RA File Number	072404000374 AM17
Licence No and	0710111126/14/02/2017

Date	
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	13 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000263AM24
RA File Number	039404001181 AM17
Licence No and Date	0310812323/03/04/2017
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	14 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000262AM24
RA File Number	039404000295 AM18
Licence No and Date	0310814908/31/07/2017
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	15 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	AETHER INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00008734AM24
RA File Number	522404000036 AM18
Licence No and Date	5210042414/23/10/2017

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-(2-HYDROXYETHYL) PHENOL	1 kg.	1	PARA CHLORO PHENOL	2.40 kg.
		2	TETRAHYDRO FURAN	1.00 kg.
		3	MEGNESSIUM TURNINGS	0.40 kg.
		4	ETHYLENE OXIDE	0.60 kg.
		5	2-METHYL TETRAHYDROFURAN	0.80 kg.

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

Case No.	16 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000265AM24
RA File Number	039404000822 AM18
Licence No and Date	0310818765/30/01/2018
Norms Committee Decision:	

The case is under consideration and TE was requested to expedite their comments.

Case No.	17 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00008733AM24
RA File Number	522404000016 AM19
Licence No and Date	5210042638/10/05/2018

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.
8-(2,6-DIETHYL-4-METHYLPHENYL)DIHYDRO-1H-PYRAZOLO[1,2-D][1,4,5]OXADIAZEPINE-7,9(2H,8H)- DIONE (M-316).	1 kg.	1	2,6-DIETHYL-4-METHYL ANILINE.	1.362 kg.
		2	SODIUM TERT BUTOXIDE	1.734 kg.
		3	PALLADIUM(II)DICHLORIDE	0.0007 kg.
		4	N-METHYL-2 PYRROLIDONE	2.15 kg.
		5	TETRAHYDROFURAN	3.90 kg.

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

Case No.	18 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	SHREE BANKEY BEHARI LAL FLAVORS

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00006890AM24
RA File Number	052404000067 AM19
Licence No and Date	0510406412/10/05/2018
Norms Committee Decision: The case is under consideration and CLA, New Delhi was requested vide DGFT (HQ) letter No.01/82/0007/AM-25/DES-III/31 dated 11/06/2024 to audit the firm and submit production/consumption data for the year 2018-19 as sought by TE within fifteen days of receipt of said letter.	

Case No.	19 / NC/3/MEET/Jun/202425/5				
Case Status	Case Approved				
Party Name	GLENMARK PHARMACEUTICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024				
HQ File Number	HQRNORM REVIW00006968AM23				
RA File Number	039404000258 AM19				
Licence No and Date	0310821966/27/06/2018				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to add export item No.7 in the previous comments and no change in the import quantity.					
Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1	Calcipotrene Ointment 60gm Taro (Calcitrene Ointment USP 0.005%) (Pack Size 60gm)	30000 Packs	1	Calcipotriol Anhydrous	2.2664 kg.
2	CALCITRENE OINTMENT 0.005% 10X5 GM (Calcitrene Ointment USP 0.005%) (Pack Size 5gm)	75000 Packs			
3	CALCITRENE OINTMENT 0.005% 60 GM (Calcitrene Ointment USP 0.005%) (Pack Size 60gm)	28000 Packs			

4	Calcipotriene Ointment 120gm Taro (Calcitrene Ointment USP 0.005%) (Pack Size 120gm)	75000 Packs			
5	Calcitrene Ointment 120gm Taro (Calcitrene Ointment USP 0.005%) (Pack Size 120gm)	45000 Packs			
6	Calcipotriene Cream 0.005% 60gm (Calcitrene Cream USP 0.005%) (Pack Size 60gm)	80000 Packs			
7	Calcipotriene Cream 0.005% 120gm (Calcitrene Cream USP 0.005%) (Pack Size 120gm)	150000 Packs			
RA concerned may take further necessary action as per above decision of NC.					

Case No.	20 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00001088AM24
RA File Number	318304000082 AM19
Licence No and Date	3110067147/20/08/2018

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.
2- PYRROLIDONE	1 kg.	1	AMMONIA ANHYDROUS	0.250 kg.
		2	GAMMA BUTYROLACTONE	1.265 kg.

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

Case No.	21 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	VINS BIOPRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00007011AM24
RA File Number	092404000363 AM19
Licence No and Date	0910066851/14/11/2018

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.
Tetanus Antitoxin IHS/BP 1000IU / 1500IU - PFS / VIALS/ Ampoules	100000 Vials	1	Tetanus Antitoxin 3000IU/ML	57 Liter

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

Case No.	22 / NC/3/MEET/Jun/202425/5
Case Status	Case Withdrawn
Party Name	TATA CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	018205001646AM19
RA File Number	039504000901 AM19
Licence No and Date	0310825645/13/12/2018

Norms Committee Decision:

The Committee considered the case as per agenda and it was observed that Norms Committee-3 in its Meeting No. NC/3/MEET/Aug/202122/7 dated 13/08/2021 has already decided to transfer the case to **Norms Committee-6** as the export product – Fossence (Oligofructose/FOS) Powder P 90/Liquid L95 comes under Food category, not Pharmaceutical. Therefore, Committee decided to **close** the case.

Case No.	23 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000260AM24
RA File Number	039404000753 AM19
Licence No and Date	0310825758/18/12/2018

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.
Efavirenz 600 mg, Lamivudine 300 mg, Tenofovir Disoproxil Fumarate 300 mg Tablets (Each Tablet contains: Efavirenz 600 mg, Tenofovir Disoproxil Fumarate 300 mg, Lamivudine 300 mg Tablets)	1 Number Tablet	1	Efavirenz	612.0 mg.
		2	Lamivudine	306.0 mg.
		3	Tenofovir Disoproxil Fumarate	306.0 mg.
		4	Croscarmellose Sodium (AC-DI-SOL) NF	123.0 mg.
		5	Microcrystalline Cellulose NF (Avicel PH 101)	297.6 mg.

		6	Magnesium Stearate NF (Vegetable Grade)	17.0 mg.
		7	Hydroxy Propyl Cellulose NF (Klucel LF)	38.4 mg.
		8	Lactose for DC (Tablettose 80/Super Tab) BP/PH Eur	199.60 mg.
		9	Silica Gel bags 3 GM Stripax R/F	Relevant packing material net to net.

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

Case No.	24 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00007594AM24
RA File Number	039404001019 AM19
Licence No and Date	0310827414/01/03/2019
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with following information / documents and proper justification of import items. Copy of amended Advance Authorisation in support of additional export and import items.	

Case No.	25 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000154AM24
RA File Number	318304000044 AM20
Licence No and Date	3110067449/20/06/2019

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Guaiacol	1 kg.	1	Phenol	1.012 kg.
		2	Methanol	0.396 kg.
		3	Hydrogen Peroxide PURITY 60%	0.80 kg.
		4	Acetone (Solvent)	0.14 kg.

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

Case No.	26 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	CONCORD BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00008666AM24
RA File Number	082404000101 AM20
Licence No and Date	0810145581/27/06/2019
Norms Committee Decision:	

The committee considered the request of firm for review/fixation of ad-hoc norms and it was observed that during the Personal Hearing held on 16/05/2024, the firm was advised to furnish the following information/documents, however, the same still not received from the firm. Therefore, it was decided that the firm may be again advised to furnish the following documents as sought earlier:

- I. **Molecular weight of input and output products.**
- II. **Percentage yield on molar basis with technical justification.**
- III. **Revised GST certificate to account for entire balanced quantity.**

Case No.	27 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000545AM25
RA File Number	092404000172 AM20
Licence No and Date	0910067749/03/07/2019

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jan/202324/20 dated 18/01/2024** against advance authorization **No.0318830783 dated N/A** , it was decided to fix ad-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.
(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride of Aminoalcohol	1 kg.	1	KRED LYOPHILIZED ENZYME POWDER	0.014 kg.

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

Case No.	28 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00008637AM24
RA File Number	039404000497 AM20
Licence No and Date	0310831894/27/09/2019
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	29 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00008636AM24
RA File Number	039404000496 AM20
Licence No and Date	0310831890/27/09/2019
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	30 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00007586AM24
RA File Number	039404000509 AM20
Licence No and Date	0310831946/01/10/2019
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
VORICONAZOLE	1 kg.	1	6-ETHYL-5-FLUORO-4-HYDROXYPYRIMIDINE	3.30 kg.
		2	METHYLENE CHLORIDE	6.87 Litre
		3	TETRA HYDRO FURAN	20.50 kg.
		4	METHANOL	1.50 Litre

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

Case No.	31 / NC/3/MEET/Jun/202425/5
Case Status	Case Withdrawn
Party Name	RELIANCE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	018205000730AM20
RA File Number	039504000661 AM20
Licence No and Date	0310832194/14/10/2019
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to transfer the case to Norms Committee-7 as norms for same export product/import items have been finalized by NC-7 in the past.	

Case No.	32 / NC/3/MEET/Jun/202425/5
Case Status	Case Withdrawn
Party Name	RELIANCE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	018205000729AM20
RA File Number	039504000662 AM20

Licence No and Date	0310832193/14/10/2019
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to transfer the case to Norms Committee-7 as norms for same export product/import items have been finalized by NC-7 in the past.	

Case No.	33 / NC/3/MEET/Jun/202425/5			
Case Status	Case Approved			
Party Name	JODAS EXPOIM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024			
HQ File Number	HQRNORM REVIW00006429AM24			
RA File Number	092404000365 AM20			
Licence No and Date	0910068207/20/11/2019			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as applied by the firm as under:				

Case No.	34 / NC/3/MEET/Jun/202425/5			
Case Status	Case Approved			
Party Name	AQUILA ORGANICS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024			

HQ File Number	HQRNORM REVIW00001077AM25													
RA File Number	039404000879 AM20													
Licence No and Date	0310834406/22/01/2020													
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/Jan/202324/20 dated 18/01/2024 against advance authorization No.0318830783 dated N/A , it was decided to fix ad-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">7-Acetyl-1,1,3,4,4,6-Hexamethyl 1,2,3,4-Tetrahydro Naphthalene</td><td rowspan="2">1 kg.</td><td>1</td><td>2,3 Dimethyl 1 Butene</td><td>0.93 kg.</td></tr><tr><td>2</td><td>PARACYMENE</td><td>0.74 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	7-Acetyl-1,1,3,4,4,6-Hexamethyl 1,2,3,4-Tetrahydro Naphthalene	1 kg.	1	2,3 Dimethyl 1 Butene	0.93 kg.	2	PARACYMENE	0.74 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
7-Acetyl-1,1,3,4,4,6-Hexamethyl 1,2,3,4-Tetrahydro Naphthalene	1 kg.	1	2,3 Dimethyl 1 Butene	0.93 kg.										
		2	PARACYMENE	0.74 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	35 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000542AM25
RA File Number	092404000540 AM20
Licence No and Date	0910068421/28/01/2020
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	36 / NC/3/MEET/Jun/202425/5
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Case Status	Case Deferred
Party Name	STRIDES ALATHUR PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	018305000750AM20
RA File Number	092404000575 AM20
Licence No and Date	0910068524/28/02/2020
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Drug Manufacturing Licence (DML) 2. Masgter Batch Formula showing net-content of imports in the export	

Case No.	37 / NC/3/MEET/Jun/202425/5
Case Status	Case Withdrawn
Party Name	RELIANCE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	018205001170AM20
RA File Number	039504001136 AM20
Licence No and Date	0310835545/20/03/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to transfer the case to Norms Committee-7 as norms for same export product/import items have been finalized by NC-7 in the past.	

Case No.	38 / NC/3/MEET/Jun/202425/5
Case Status	Case Withdrawn
Party Name	RELIANCE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	018205001184AM21
RA File Number	039504001243 AM20
Licence No and Date	0310835621/18/04/2020

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to transfer the case to **Norms Committee-7** as norms for same export product/import items have been finalized by NC-7 in the past.

Case No.	39 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00005893AM24
RA File Number	039504000017 AM21
Licence No and Date	0310835789/21/04/2020
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Drug Manufacturing License (DML) with approved composition. 2. Master-Batch Formula.	

Case No.	40 / NC/3/MEET/Jun/202425/5
Case Status	Case Withdrawn
Party Name	RELIANCE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	018205001220AM21
RA File Number	039504001109 AM20
Licence No and Date	0310835972/26/04/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to transfer the case to Norms Committee-7 as norms for same export product/import items have been finalized by NC-7 in the past.	

Case No.	41 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	ARENE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00006628AM24
RA File Number	092404000024 AM21
Licence No and Date	0910068681/28/04/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm was called for Personal Hearing on 16/05/2024, but the firm could not appear before Norms Committee. After that it was decided to grant one more opportunity to the firm for a Personal Hearing with relevant documents/information.	

Case No.	42 / NC/3/MEET/Jun/202425/5
Case Status	Case Withdrawn
Party Name	RELIANCE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	018205001254AM21
RA File Number	039504000020 AM21
Licence No and Date	0310836081/04/05/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to transfer the case to Norms Committee-7 as norms for same export product/import items have been finalized by NC-7 in the past.	

Case No.	43 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00008587AM24
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 it was decided to fix ad-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)	3.465 kg.

Note: The ad-hoc norms fixed for one time basis.

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

Case No.	44 / NC/3/MEET/Jun/202425/5
Case Status	Case Withdrawn
Party Name	RELIANCE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	018205001364AM21
RA File Number	039504000105 AM21
Licence No and Date	0310836584/09/06/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to transfer the case to Norms Committee-7 as norms for same export product/import items have been finalized by NC-7 in the past.	

Case No.	45 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred

Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00005894AM24
RA File Number	039504000137 AM21
Licence No and Date	0310836741/18/06/2020
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Drug Manufacturing License (DML) with approved composition.	

Case No.	46 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000546AM25
RA File Number	092404000185 AM21
Licence No and Date	0910068991/22/07/2020
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	47 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	HALDIA PETROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	018205001724AM21
RA File Number	022404000087 AM21
Licence No and Date	0210210144/06/10/2020
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.
Benzene (from olefinic complex)	1 MT	1	Light Naphtha	1.194 MT

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

Case No.	48 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00004138AM23
RA File Number	092404000365 AM21
Licence No and Date	0910069368/22/10/2020
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	49 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	018205001853AM21
RA File Number	342404000223 AM21
Licence No and Date	3410046549/13/11/2020
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.
Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% (15 gm Tube).	1 Number	1	Nystatin USP	238.65 mg
Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% (30 gm Tube).	1 Number	2	Nystatin USP	477.30 mg.
Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% (60 gm Tube)	1 Number	3	Nystatin USP	954.61 mg.
Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% (15 gm Tube)	1 Number	4	Nystatin USP	238.65 mg.
Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% (30 gm Tube).	1 Number	5	Nystatin USP	477.30 mg.
Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% (60 gm Tube)	1 Number	6	Nystatin USP	954.61 mg

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

Case No.	50 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	MAC-CHEM PRODUCTS (INDIA) PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024

and Date	
HQ File Number	HQRNORM REVIW00005491AM24
RA File Number	NA
Licence No and Date	0311000185/17/12/2020
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	51 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000254AM24
RA File Number	03AA04011698 AM21
Licence No and Date	0311000235/21/12/2020
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	52 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000543AM25
RA File Number	09AA04003656 AM21
Licence No and Date	0911000173/11/01/2021
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	53 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00008364AM24
RA File Number	05AA04025954 AM21
Licence No and Date	0511001043/02/02/2021
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Drug Manufacturing Licence (DML). 2. Master-Batch Formula 3. Certificate of Analysis (CoA) of import item.	

Case No.	54 / NC/3/MEET/Jun/202425/5										
Case Status	Case Approved										
Party Name	ORIENTAL AROMATICS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024										
HQ File Number	HQRNORM REVIW00008140AM24										
RA File Number	03AA04029725 AM21										
Licence No and Date	0311002554/16/03/2021										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>MYSORNAOL AB18019</td><td>1 kg.</td><td>1</td><td>Alpha Pinene</td><td>1.813 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MYSORNAOL AB18019	1 kg.	1	Alpha Pinene	1.813 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
MYSORNAOL AB18019	1 kg.	1	Alpha Pinene	1.813 kg.							

(Perfumery Compound)		2	Sec butanol	0.425 kg.
		3	Aluminium Tri Sec Butoxide	0.08 kg.
		4	Di -N- Butylamine	0.03 kg.

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

Case No.	55 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00004030AM23
RA File Number	03AA04033623 AM21
Licence No and Date	0311003093/08/04/2021

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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ISO BUTYL BROMIDE (1-BROMO -2- METHYL PROPANE)	1 kg.	1	ISO BUTANOL	1.08 kg.
		2	LIQUID BROMINE	1.16 kg

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

Case No.	56 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00122419AM22
RA File Number	34AA04003768 AM22
Licence No and Date	3411000762/23/06/2021
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Complete Chemistry. 2. Material balance & Yield.	

Case No.	57 / NC/3/MEET/Jun/202425/5													
Case Status	Case Approved													
Party Name	HIKAL LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024													
HQ File Number	HQRNORM REVIW00004361AM24													
RA File Number	34AA04002140 AM22													
Licence No and Date	3411000771/28/06/2021													
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:-														
<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">Probenazole</td><td rowspan="2">1 kg.</td><td>1</td><td>Insoluble saccharin (Saccharin imide)</td><td>1.013 kg.</td></tr><tr><td>2</td><td>Allyl alcohol</td><td>0.30 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Probenazole	1 kg.	1	Insoluble saccharin (Saccharin imide)	1.013 kg.	2	Allyl alcohol	0.30 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Probenazole	1 kg.	1	Insoluble saccharin (Saccharin imide)	1.013 kg.										
		2	Allyl alcohol	0.30 kg.										

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

Case No.	58 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000544AM25
RA File Number	09AA04007265 AM22
Licence No and Date	0911001194/12/07/2021
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	59 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00137048AM22
RA File Number	34AA04005105 AM22
Licence No and Date	3411000838/12/07/2021
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it has been observed that the firm has furnished incomplete documents/information as sought by the Committee in the NC-3 meeting held on 28/07/2023. Therefore, it has been decided that the firm may be asked to furnish the following documents/information:- 1. Complete chemistry, Molecular weight and percentage yield on molar basis. 2. Certificate of Analysis (CoA) of export product.	

Case No.	60 / NC/3/MEET/Jun/202425/5																			
Case Status	Case Approved																			
Party Name	AETHER INDUSTRIES LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024																			
HQ File Number	HQRNORM REVIW00008736AM24																			
RA File Number	52AA04008175 AM22																			
Licence No and Date	5211001047/26/07/2021																			
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:-																				
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="4">BIFENTHRIN ALCOHOL</td><td rowspan="4">1 kg.</td><td>1</td><td>2 6 DICHLOROTOLUENE</td><td>1.90 kg.</td></tr><tr><td>2</td><td>TETRAHYDROFURAN</td><td>2.00 kg.</td></tr><tr><td>3</td><td>MAGNESIUM TURNINGS</td><td>0.60 kg.</td></tr><tr><td>4</td><td>n HEPTANE</td><td>1.77 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	BIFENTHRIN ALCOHOL	1 kg.	1	2 6 DICHLOROTOLUENE	1.90 kg.	2	TETRAHYDROFURAN	2.00 kg.	3	MAGNESIUM TURNINGS	0.60 kg.	4	n HEPTANE	1.77 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
BIFENTHRIN ALCOHOL	1 kg.	1	2 6 DICHLOROTOLUENE	1.90 kg.																
		2	TETRAHYDROFURAN	2.00 kg.																
		3	MAGNESIUM TURNINGS	0.60 kg.																
		4	n HEPTANE	1.77 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	61 / NC/3/MEET/Jun/202425/5			
Case Status	Case Approved			
Party Name	SUNDYOTA NUMANDIS PROBIOCEUTICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024			
HQ File Number	HQRNORM REVIW00004161AM24			
RA File Number	08AA04021121 AM22			
Licence No and	0811002324/16/08/2021			

Date	
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed that ad-hoc norms had already been fixed in respect of Advance Authorisation No. 0811002324 dated 16/08/2021 by the Committee in its meeting held on 06/06/2024. Therefore, it was decided to close the application of the firm.	

Case No.	62 / NC/3/MEET/Jun/202425/5															
Case Status	Case Approved															
Party Name	FRESENIUS KABI ONCOLOGY LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024															
HQ File Number	HQRNORM APPLY 00165403AM22															
RA File Number	05AA04062260 AM22															
Licence No and Date	0511004178/18/08/2021															
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:-																
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Ropivacaine Hydrochloride Monohydrate(API)</td><td>1 kg.</td><td>1</td><td>(S)-2',6' Pipecoloxylidide</td><td>0.872 kg.</td></tr><tr><td>Ropivacaine Hydrochloride Anhydrous(API)</td><td>1 kg.</td><td>2</td><td>(S)-2',6'Pipecoloxylidide</td><td>0.923 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ropivacaine Hydrochloride Monohydrate(API)	1 kg.	1	(S)-2',6' Pipecoloxylidide	0.872 kg.	Ropivacaine Hydrochloride Anhydrous(API)	1 kg.	2	(S)-2',6'Pipecoloxylidide	0.923 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Ropivacaine Hydrochloride Monohydrate(API)	1 kg.	1	(S)-2',6' Pipecoloxylidide	0.872 kg.												
Ropivacaine Hydrochloride Anhydrous(API)	1 kg.	2	(S)-2',6'Pipecoloxylidide	0.923 kg.												
RA concerned may take further necessary action as per above decision of NC.																

Case No.	63 / NC/3/MEET/Jun/202425/5				
Case Status	Case Approved				
Party Name	SRF LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024				

HQ File Number	HQRNORM REVIW00007920AM24
RA File Number	05AA04070230 AM22
Licence No and Date	0511004557/06/09/2021

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/Apr/202425/2 dated 30/04/2024** against advance authorization **No.0511015715 dated 09/11/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

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

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

Case No.	64 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	SRF LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00008056AM24
RA File Number	05AA04076999 AM22
Licence No and Date	0511004742/15/09/2021

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/Apr/202425/2 dated 30/04/2024** against advance authorization **No.0511015715 dated 09/11/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

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

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

Case No.	65 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
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 observed that during the Personal Hearing held on 16/05/2024, the firm was advised to furnish the following information/documents, however, the same still not received from the firm. Therefore, it was decided that the firm may be again advised to furnish the following documents as sought earlier: I. Complete batch chemical reaction showing description of export and import item along with percentage yield on molar basis. II. Certificate of Analysis (CoA) of import item to explain the complete description of import item No.1	

Case No.	66 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00193597AM22
RA File Number	03AA04097753 AM22
Licence No and Date	0311007198/25/09/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents from the firm:- 1. Certificate of Analysis (CoA) of import item from Foreign Supplier showing particle size of import. 2. Copy of Bill of Entry in support of 1 above.	

Case No.	67 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024

and Date															
HQ File Number	HQRNORM REVIW00006071AM24														
RA File Number	03AA040106642 AM22														
Licence No and Date	0311007268/28/09/2021														
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:- <table border="1" data-bbox="197 641 1430 914"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>BRIMONIDINE EYE DROPS 0.2% w/v, 5 ML Vial.</td> <td>1 Number</td> <td>1</td> <td>BRIMONIDINE L TARTRATE</td> <td>10.2 mg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	BRIMONIDINE EYE DROPS 0.2% w/v, 5 ML Vial.	1 Number	1	BRIMONIDINE L TARTRATE	10.2 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.											
BRIMONIDINE EYE DROPS 0.2% w/v, 5 ML Vial.	1 Number	1	BRIMONIDINE L TARTRATE	10.2 mg.											

Case No.	68 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	KRITI NUTRIENTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00001036AM25
RA File Number	56AA04005794 AM22
Licence No and Date	5611000556/12/10/2021
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete Certificate of Analysis (CoA) of import items from Foreign Supplier.	

Case No.	69 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	LUPIN LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00005265AM24
RA File Number	03AA040109357 AM22
Licence No and Date	0311007760/18/10/2021

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.
Amlodipine Besylate and Benazepril Hydrochloride Cap USP5/ 40mg	1 Number	1	T-BUTYL, 3S-AMINO-2,3,4,5-TETRAHYDRO-1-H-(1) BENAZEPIN-2-ONE-1-ACETATE	32.97 mg.
		2	(R)-2-HYDROXY-4-PHENYLBUTANOIC ACID ETHYL ESTER	22.726 mg.
Amlodipine Besylate and Benazepril Hydrochloride Cap USP10/ 40mg	1 Number	3	T-BUTYL, 3S-AMINO-2,3,4,5-TETRAHYDRO-1-H-(1) BENAZEPIN-2-ONE-1-ACETATE	32.97 mg.
		4	R)-2-HYDROXY-4-PHENYLBUTANOIC ACID ETHYL ESTER	22.726 mg.
Amlodipine and Benazepril Hydrochloride Cap USP5/ 10mg	1 Number	5	T-BUTYL, 3S-AMINO-2,3,4,5-TETRAHYDRO-1-H-(1) BENAZEPIN-2-ONE-1-ACETATE	8.24 mg.
		6	(R)-2-HYDROXY-4-PHENYLBUTANOIC ACID ETHYL ESTER	5.681 mg.

Amlodipine and Benazepril Hydrochloride Cap USP 5/20 mg	1 Number	7	T-BUTYL, 3S-AMINO-2,3,4,5-TETRAHYDRO-1-H-(1) BENAZEPIN-2-ONE-1-ACETATE	16.483 mg.
		8	((R)-2-HYDROXY-4-PHENYLBUTANOIC ACID ETHYL ESTER R)-2-HYDROXY-4-PHENYLBUTANOIC ACID ETHYL ESTER	11.363 mg.
Amlodipine Besylate and Benazepril Hydrochloride CAP USP10/ 20mg	1 Number	9	T-BUTYL, 3S-AMINO-2,3,4,5-TETRAHYDRO-1-H-(1) BENAZEPIN-2-ONE-1-ACETATE	16.483 mg.
		10	(R)-2-HYDROXY-4-PHENYLBUTANOIC ACID ETHYL ESTER	11.363 mg.
Amlodipine Besylate and Benazepril Hydrochloride Cap 2.5/ 10mg	1 Number	11	T-BUTYL, 3S-AMINO-2,3,4,5-TETRAHYDRO-1-H-(1) BENAZEPIN-2-ONE-1-ACETATE	8.24 mg.
		12	(R)-2-HYDROXY-4-PHENYLBUTANOIC ACID ETHYL ESTER	5.681 mg.

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

Case No.	70 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00220580AM22

RA File Number	05AA04091063 AM22
Licence No and Date	0511005553/21/10/2021
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Molecular weight at each step not given. 2. Percentage yield on molar basis for each step.	

Case No.	71 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00220582AM22
RA File Number	05AA04091028 AM22
Licence No and Date	0511005555/21/10/2021
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- i. Molecular weight at each step not given. ii. Percentage yield on molar basis for each step.	

Case No.	72 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00239769AM22
RA File Number	09AA04001389 AM22
Licence No and Date	0911001808/02/11/2021

Norms Committee Decision:

The firm vide e-mail dated 27/06/2024 has informed that they have surrendered their above license. In view of e-mail of firm, the Committee decided to **close** the application of the firm.

Case No.	73 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00006176AM24
RA File Number	03AA040119771 AM22
Licence No and Date	0311008387/10/11/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BRIMONIDINE EYE DROPS 0.2% w/v, 5 ML Vial.	1 Number	1	BRIMONIDINE L TARTRATE	10.2 mg.

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

Case No.	74 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00005991AM24
RA File Number	03AA04014060 AM22
Licence No and	0311008817/24/11/2021

Date					
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Apr/202425/1 dated 10/04/2024 against advance authorization No. 0311008775 dated 23/11/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.
DIMETHYL ACETOACETAMIDE (DIMETHYL ACETOACETAMIDE (DMAAA))		1 kg.	1	Acetic Acid	0.90 kg.
			2	Dimethyl Amine	0.45 kg.
RA concerned may take further necessary action as per above decision of NC.					

Case No.	75 / NC/3/MEET/Jun/202425/5				
Case Status	Case Approved				
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024				
HQ File Number	HQRNORM REVIW00005995AM24				
RA File Number	03AA04014502 AM22				
Licence No and Date	0311009117/02/12/2021				
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.
N-BUTYLACETOACETATE ESTER		1 kg.	1	Acetic Acid	0.95 kg.
			2	N-BUTANOL	0.50 kg.

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

Case No.	76 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00008200AM24
RA File Number	05AA040108247 AM22
Licence No and Date	0511006681/07/12/2021
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Drug Manufacturing Licence (DML) with approved composition. 2. Master-Batch Formula for each export. 3. Certificate of Analysis (CoA) of import item.	

Case No.	77 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00293146AM22
RA File Number	34AX04000029 AM22
Licence No and Date	3411001569/21/12/2021
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:-	

1. **Certificate of Analysis (CoA) of both import and export items giving clearly percentage of its purity.**
2. **Sample of Shipping Bills and Bill of Entry of the export products and statement of export import of the Authorisation.**

Case No.	78 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00008265AM24
RA File Number	05AX04000189 AM22
Licence No and Date	0511007079/21/12/2021
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- i. Drug Manufacturing Licence (DML) with approved composition. ii. Master-Batch Formula for each export. iii. Certificate of Analysis (CoA) of import item.	

Case No.	79 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00006188AM24
RA File Number	03AX04000256 AM22
Licence No and Date	0311009818/27/12/2021
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.
GENTAMICIN EAR/EYE DROPS 10 ML, 0.3% w/v	1 Number	1	GENTAMICIN SULPHATE	30.6 mg.

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

Case No.	80 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00299896AM22
RA File Number	34AX04000090 AM22
Licence No and Date	3411001598/28/12/2021

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.
CLOMIPRAMINE HCL CAP USP 25 MG	1 Number	1	Clomipramine Hydrochloride USP	25.50 mg.
		2	Microcrystalline Cellulose (Avicel PH 301)	148.80 mg.
		3	Pregelatinized starch (Starch 1500 LM)	39.60 mg.
		4	Colloidal silicon dioxide (Aerosil 200 Pharma)	2.20 mg.
		5	Magnesium Stearate	4.40 mg.

			(Vegetable Source)	
CLOMIPRAMINE HCL CAP USP 50 MG	1 Number	6	Clomipramine Hydrochloride USP	51.00 mg.
		7	Microcrystalline Cellulose (Avicel PH 301)	210.70 mg.
		8	Pregelatinized starch (Starch 1500 LM)	59.40 mg.
		9	Colloidal silicon dioxide (Aerosil 200 Pharma)	3.30 mg.
		10	Magnesium Stearate (Vegetable Source)	6.60 mg.
CLOMIPRAMINE HCL CAP USP 75 MG	1 Number	11	Clomipramine Hydrochloride USP	76.50 mg.
		12	Microcrystalline Cellulose (Avicel PH 301)	205.45 mg.
		13	Pregelatinized starch (Starch 1500 LM)	63.90 mg.
		14	Colloidal silicon dioxide (Aerosil 200 Pharma)	3.55 mg.
		15	Magnesium Stearate (Vegetable Source)	7.10 mg.

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

Case No.	81 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
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 case as per agenda and it was observed that the firm was asked to give Chemical reaction of the process with yield, and production/consumption data of specific items of export, several times but they have not given the same. Due to this, the Committee decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	82 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	PANACEA BIOTEC PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00005946AM24
RA File Number	05AX04000321 AM22
Licence No and Date	0511007823/11/01/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	83 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00006821AM24
RA File Number	038504000145 AM21
Licence No and Date	0311010587/17/01/2022
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject	

the case maintaining the **status quo**.

Case No.	84 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00345828AM22
RA File Number	09AX04000205 AM22
Licence No and Date	0911002465/07/02/2022

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.
Tofacitinib Citrate	1 kg.	1	4-CHLORO-7H PYRROLO[2,3-D]PYRIMIDINE	1.00 kg.
		2	(3R,4R)-N,4-DIMETHYL -1-(PHENYLMETHYL) -3-PIPERIDINAMINEHYDROCHLORIDE	1.72 kg.

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

Case No.	85 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00350237AM22
RA File Number	05AX04000943 AM22
Licence No and Date	0511008753/10/02/2022

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:-

a. Norms for 1 Number Tablet.

Bulk Drug	Quantity in mg.	
	Export item no.1	Export item no.2
Buprenorphine Hydrochloride	2.04 mg.	8.16 mg.
Naloxone Hydrochloride	0.51 mg.	2.04 mg.

b. Raw Material proposed for 1 kg. Buprenorphine Hydrochloride

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Buprenorphine Hydrochloride	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	Methane 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.

c. Raw Material proposed for 1 kg. Naloxone Hydrochloride

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Naloxone Hydrochloride	1 kg.	12	Noroxymorphone	1.23 kg.
		13	Methylene Chloride	7.45 kg.

Note: RA may work-out the import entitlement of all inputs as per (a), (b) & (c) above on pro-rata basis.

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

Case No.	86 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	GANGWAL HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00356909AM22
RA File Number	03AX04001205 AM22
Licence No and	0311011422/16/02/2022

Date	
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Export description is vogue and does not indicate percentage DHA in export. 2. Import item No.1 is confusing as it does not indicate percentage Assay. 3. Whether import and export are Oil Powder. If so, please get the licence amended as per 1 to 3 above.	

Case No.	87 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00006822AM24
RA File Number	03AX04000957 AM22
Licence No and Date	0311011997/28/02/2022
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	88 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	KRITI NUTRIENTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00001037AM25
RA File Number	56AX04000172 AM23
Licence No and Date	5611001168/15/09/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of	

the TE, it was decided to call for following information/documents from the firm:-

Complete Certificate of Analysis (CoA) of import items from Foreign Supplier.

Case No.	89 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	CANPEX CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00003225AM23
RA File Number	31AX04000170 AM23
Licence No and Date	3111001703/20/09/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CYANAMIDE 50% SOLUTION	1 kg.	1	CALCIUM CYANAMIDE (Purity 63% as per CoA)	1.913 kg.

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

Case No.	90 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM APPLY 00003358AM23
RA File Number	03AX04002988 AM23

Licence No and Date	0311018145/25/09/2022
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite their comments.	

Case No.	91 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	KRITI NUTRIENTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00001038AM25
RA File Number	56AX04000363 AM23
Licence No and Date	5611001525/02/02/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete Certificate of Analysis (CoA) of import items from Foreign Supplier.	

Case No.	92 / NC/3/MEET/Jun/202425/5
Case Status	Case Approved
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00001133AM25
RA File Number	03AX04000744 AM24
Licence No and Date	0311023755/20/05/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to revise ad-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, 6-Dichloro Benzoyl chloride	1 kg.	1	2,6-Dichloro Benzaldehyde	1.185 kg.

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

Case No.	93 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00001056AM25
RA File Number	09AX04000845 AM23
Licence No and Date	0911005139/01/06/2023
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that norms apply in the two advance licences are different and the firm has now represented against the norms ratified by the committee on the basis of comparative data for above referred licences. The Committee also observed that there is still confusion in the import quantity for key raw material i.e. <i>Pencilin G</i> as the firm has not so far get their licence amended for higher norms. The Committee felt that the firm may be called for Personal Hearing and explain their case in details alongwith necessary documents. The firm is also advised to bring actual production/consumption data relevant to these two licence separately alongwith copy of Shipping Bills and Bill of Entry.	

Case No.	94 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00001053AM25
RA File Number	09AX04000025 AM24
Licence No and	0911005223/19/06/2023

Date	
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that norms apply in the two advance licences are different and the firm has now represented against the norms ratified by the committee on the basis of comparative data for above referred licences. The Committee also observed that there is still confusion in the import quantity for key raw material i.e. <i>Pencilin G</i> as the firm has not so far get their licence amended for higher norms. The Committee felt that the firm may be called for Personal Hearing and explain their case in details alongwith necessary documents. The firm is also advised to bring actual production/consumption data relevant to these two licence separately alongwith copy of Shipping Bills and Bill of Entry.	

Case No.	95 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000801AM25
RA File Number	09AX04000551 AM24
Licence No and Date	0911005810/20/09/2023
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	96 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	LINCOLN PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000899AM25
RA File Number	08AX04001563 AM24
Licence No and Date	0811009996/20/11/2023
Norms Committee Decision:	

The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to **reject** the case maintaining the **status quo**.

Case No.	97 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000628AM25
RA File Number	03AX04003995 AM24
Licence No and Date	0311029148/06/12/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Certificate of Analysis (CoA) of import item indicating percentage content of Alpha Pinen. 2. Prodeuction/consumption data duly certified by Auditor of the firm. 3. Percentage puriety of import and export.	

Case No.	98 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000727AM25
RA File Number	03AX04004322 AM24
Licence No and Date	0311029676/27/12/2023
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	99 / NC/3/MEET/Jun/202425/5
Case Status	Case Rejected
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00001103AM25
RA File Number	03AX04004600 AM24
Licence No and Date	0311030078/10/01/2024
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	100 / NC/3/MEET/Jun/202425/5
Case Status	Case Deferred
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Jun/ 202425/ 5 and 14/06/2024
HQ File Number	HQRNORM REVIW00000622AM25
RA File Number	34AX04000854 AM24
Licence No and Date	3411004626/16/02/2024
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Percentae puriety of import and export alongwith Certificatge of Analysis (CoA). 2. Production / consumption data duty certified by Auditor of the firm. 3. Percentage yield of reaction and fractional distillation.	