



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

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

(DES - III SECTION)**MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Aug/202324/11**DATED:** 22/08/2023Please 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/Aug/202324/11 dated 22/08/2023 of Norms Committee - III for the year 2023-24 was held on 22/08/2023 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/Aug/202324/11																
Case Status	Case Approved																
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023																
HQ File Number	HQRNORM APPLY 00000449AM24																
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"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Sulfadoxine</td> <td rowspan="2">1 Kg.</td> <td>1</td> <td>4,6 Dichloro 5-Methoxy Pyrimidine (DCMP)</td> <td>0.78 kg.</td> </tr> <tr> <td>2</td> <td>SULFANILAMIDE</td> <td>0.90 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Sulfadoxine	1 Kg.	1	4,6 Dichloro 5-Methoxy Pyrimidine (DCMP)	0.78 kg.	2	SULFANILAMIDE	0.90 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.													
Sulfadoxine	1 Kg.	1	4,6 Dichloro 5-Methoxy Pyrimidine (DCMP)	0.78 kg.													
		2	SULFANILAMIDE	0.90 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	2 / NC/3/MEET/Aug/202324/11								
Case Status	Case Approved								
Party Name	ZYDUS LIFESCIENCES LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023								
HQ File Number	HQRNORM APPLY 00000763AM24								
RA File Number	NA								
Licence No and Date	NA								
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Aug/202122/7 dated 13/08/2021 against advance authorization No.0810143923 dated 20/11/2018 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-									
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty.</th> </tr> </thead> <tbody> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty.
Export Product	Qty.	Sl. No.	Import Items	Qty.					

AZITHROMYCIN ORAL SUSPENSION USP 100MG/5ML (300MG/15ML BOTTLE) ((ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP EQUIVALENT TO AZITHROMYCIN USP - NET WT. 265.196 KGS))	1 Number	1	AZITHROMYCIN DIHYDRATE USP	330.12 mg.
		2	SUCROSE NF FINE GRADE (COMPRESSUC PS)	11616.00 mg.
AZITHROMYCIN ORAL SUSPENSION USP 200MG/5ML (600MG/15ML BOTTLE) ((ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP EQUIVALENT TO AZITHROMYCIN USP - NET WT. 742.553 KGS))	1 Number	1	AZITHROMYCIN DIHYDRATE USP	660.24 mg.
		2	SUCROSE NF FINE GRADE (COMPRESSUC PS)	11616.00 mg.
AZITHROMYCIN ORAL SUSPENSION USP 200MG/5ML (900MG/22.5ML BOTTLE) ((ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP EQUIVALENT TO AZITHROMYCIN USP - NET WT. 836.953 KGS))	1 Number	1	AZITHROMYCIN DIHYDRATE USP	990.36 mg.
		2	SUCROSE NF FINE GRADE (COMPRESSUC PS)	17424.00 mg.
AZITHROMYCIN ORAL SUSPENSION USP 200MG/5ML (1200MG/30ML BOTTLE) ((ACTIVE INGREDIENT: AZITHROMYCIN DIHYDRATE USP EQUIVALENT TO AZITHROMYCIN USP - NET WT. 1275.898 KGS))	1 Number	1	AZITHROMYCIN DIHYDRATE USP	1320.48 mg.
		2	SUCROSE NF FINE GRADE (COMPRESSUC PS)	23232.00 mg.

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

Case No.	3 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	PAYAL POLYPLAST PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM APPLY 00004181AM23			
RA File Number	NA			
Licence No and Date	NA			
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.0510401740 dated 21/02/2017, 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:-				

PLASTICIZER (DI ISONONYL PHTHALATE) (OILY LIQUID PHTHALATE EASTER)	1 kg.	1	PHTHALI ANHYDRIDE	0.372 kg.
		2	ISO NONANOL	0.726 kg.

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

Case No.	4 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	INNOVASSYNTH TECHNOLOGIES (INDIA) LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00004451AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	5 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004198AM24
RA File Number	092404000579 AM12
Licence No and Date	0910051360/21/02/2012
Norms Committee Decision:	
The Committee considered the 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.	6 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	MYLAN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00003162AM23
RA File Number	092404000288 AM13
Licence No and Date	0910053905/26/09/2012
Norms Committee Decision:	

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

Case No.	7 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	BAYER CROPSCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004885AM24
RA File Number	039404000797 AM14
Licence No and Date	0310772503/28/02/2014

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.
SOD (N2-(1,1-DIMETHYL-2-METHYLSULFINYLETHYL)(-N1-(2-METHYL-4-(1,2,2,2-TETRAFLUORO-1-(TRIFLUOROMETHYL)ETHYL)PHENYL)PHTHALAMIDE)	1 Kg	1	PHTHALOYL DICHLORIDE (PDC)	0.461 kg
		2	2-METHYL-1-METHYLTHIO-2-PROPANAMINE(SAA)	0.283 kg
		3	2-METHYL-4-HEPTAFLUOROISOPROPYLAMINE(RFA)	0.581 kg
		4	TOLUENE	0.190 kg

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

Case No.	8 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005396AM23
RA File Number	NA
Licence No and Date	0510386128/09/05/2014

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.NC/3/MEET/Nov/20223/12 dated 18/11/2022** against advance authorization **No.0510408806 dated 06/12/2018**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
DI OCTYL TERE PHTHALATE (DOTP)	1 kg.	1	PURE TERE PHTHALIC ACID	0.447 kg.
		2	2 ETHYL HEXANOL	0.680 kg.

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

Case No.	9 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005418AM23
RA File Number	NA
Licence No and Date	0710106181/25/07/2014

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.
CAL - SUP TABLETS CALCIUM CARBONATE 1250 MG + GLYCINE 535.7 MG (No of tabs -4000000) (Glycine - 2142.800 Kgs + Calcium - 5000.000 Kgs)	1 Number	1	GLYCINE USP/BP/EP	535.7 mg.
		2	CALCIUM CARBONATE DENSE BP/USP	1275.00 mg.

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

Case No.	10 / NC/3/MEET/Aug/202324/11
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Case Status	Case Approved
Party Name	BAYER CROPSCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004881AM24
RA File Number	039404000405 AM15
Licence No and Date	0310788397/26/08/2014

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.
SOD = N2 - (1, 1-DIMETHYL-2-METHYLSULFINYLETHYL)-N1-(2-METHYL-4-(1,2,2,2-TETRAFLUORO(-1-(TRIFLUOROMETHYL)ETHYL)PHENYL)PHTHALAMIDE)	1 Kg	1	PHTHALOYL DICHLORIDE (PDC)	0.5000 kg
		2	2-METHYL-1-METHYLTHIO-2-PROPANAMINE (SAA)	0.3090 kg
		3	2-METHYL-4-HEPTAFLUOROISOPROPYLAMINE(RFA)	0.5645 kg
		4	TOLUENE	0.200 kg

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

Case No.	11 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00003010AM24
RA File Number	092404000374 AM15
Licence No and Date	0910061119/17/10/2014

Norms Committee Decision:

The Committee considered the 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.	12 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	BAYER CROPSCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004883AM24
RA File Number	039404000710 AM15
Licence No and Date	0310791177/18/11/2014

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.
SOD = N2 - (1, 1-DIMETHYL-2-METHYLSULFINYLETHYL)-N1-(2-METHYL-4-(1,2,2,2-TETRAFLUORO(-1-(TRIFLUOROMETHYL)ETHYL)PHENYL)PHTHALAMIDE)	1 Kg	1	PHTHALOYL DICHLORIDE (PDC)	0.5000 kg
		2	2-METHYL-1-METHYLTHIO-2-PROPANAMINE (SAA)	0.3090 kg
		3	2-METHYL-4-HEPTAFLUOROISOPROPYLAMINE(RFA)	0.5645 kg
		4	TOLUENE	0.200 kg

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

Case No.	13 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	BAYER CROPSCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004884AM24
RA File Number	039404000930 AM15
Licence No and Date	0310793539/03/02/2015

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.
SOD = N2 - (1, 1-DIMETHYL-2-METHYLSULFINYLETHYL)-N1-(2-METHYL-4-(1,2,2,2-TETRAFLUORO(-1-(TRIFLUOROMETHYL)ETHYL)PHENYL)PTHALAMIDE)	1 Kg	1	PHTHALOYL DICHLORIDE (PDC)	0.5000 kg
		2	2-METHYL-1-METHYLTHIO-2-PROPANAMINE (SAA)	0.3090 kg
		3	2-METHYL-4-HEPTAFLUOROISOPROPYLAMINE(RFA)	0.5645 kg
		4	TOLUENE	0.200 kg

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

Case No.	14 / NC/3/MEET/Aug/202324/11
Case Status	Case Rejected
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004183AM23
RA File Number	522404000058 AM15
Licence No and Date	5210041428/13/02/2015
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	15 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004477AM24
RA File Number	092404000028 AM16

Licence No and Date	0910061955/01/05/2015			
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.
SOFOSBUVIR	1 kg.	1	Cytidine,N-benzoyl-2-deoxy-2-fluoro-2-methyl-3,5-dibenzoate,(2r)	Not required
		2	2-deoxy-2-fluoro-2-C-methyluridine	0.87 kg.
		3	N-[(S)-(2,3,4,5,6-Pentafluorophenoxy) phenoxyphosphinyl]-L-alanine 1-methylethyl ester	Not required
		4	L-Alanine isopropyl ester hydrochloride	1.80 kg.
		5	Phenyl dichlorophosphate	1.58 kg.
		6	Pentafluorophenol	1.16 kg.
Note: The above norms are for regularization and closure purpose only.				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	16 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	OPTIMUS DRUGS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM REVIW00004478AM24			
RA File Number	092404000223 AM16			
Licence No and Date	0910062361/22/07/2015			
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.

Simeprevir	1 kg.	1	(2R,3aR,10Z,11aS,12aR,14aR)-2,3,3a,4,5,6,7,8,9,11a,12,13,14,14a-Tetradecahydro-2-[[7-methoxy-8-methyl-2-[4-(1-methylethyl)-2-thiazolyl]-4-quinolinyl]oxy]-5-methyl-4,14-dioxocyclopenta[c]cyclopropa[g][1,6]diazacyclotetradecine-12a(1H)-carboxylic acid	1.309 kg.
		2	(2R,3aR,10Z,11aS,12aR,14aR)-2,3,3a,4,5,6,7,8,9,11a,12,13,14,14a-Tetradecahydro-2-[[7-methoxy-8-methyl-2-[4-(1-methylethyl)-2-thiazolyl]-4-quinolinyl]oxy]-5-methyl-4,14-dioxocyclopenta[c]cyclopropa[g][1,6]diazacyclotetradecine-12a(1H)-carboxamide	Not Required

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

Case No.	17 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004182AM23
RA File Number	522404000034 AM16
Licence No and Date	5210041610/14/08/2015
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. Complete Chemistry with chemical reaction, indicating molecular weight of both reactant and proeducts, giving yield of the reaction. 2. Justification of wastage at each stage of reaction. 3. Production/consumption data duly certified by CA.	

Case No.	18 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	BAYER CROPSCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004882AM24
RA File Number	039404000443 AM16
Licence No and Date	0310800060/05/11/2015
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.
SOD = N2 - (1, 1-DIMETHYL-2-METHYLSULFINYLETHYL)-N1-(2-METHYL-4-(1,2,2,2-TETRAFLUORO (-1-(TRIFLUOROMETHYL)ETHYL)PHENYL)PHTHALAMIDE)	1 Kg	1	PHTHALOYL DICHLORIDE (PDC)	0.5000 kg
		2	2-METHYL-1-METHYLTHIO-2-PROPANAMINE (SAA)	0.3090 kg
		3	2-METHYL-4-HEPTAFLUOROISOPROPYLAMINE(RFA)	0.5645 kg
		4	TOLUENE	0.200 kg

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

Case No.	19 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004227AM24
RA File Number	222404000101 AM16
Licence No and Date	2210015410/09/02/2016
Norms Committee Decision:	
The committee has considered the case of the firm as per agenda and it has been observed that name of import item has already been corrected in the Meeting No. 10/AM19 dated 13.11.2018 . Therefore, the committee decided to withdraw the application of the firm. The firm may also check the Minutes of the Meeting dated 13.11.2018 uploaded in the DGFT website Portal.	

Case No.	20 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004184AM23
RA File Number	522404000042 AM17

Licence No and Date	5210042032/30/09/2016
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Stage wise yield of the reaction giving justification of wastage at each stage of reaction. 2. By-product value, if any.	

Case No.	21 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	ARIHANTA SIDDHA LABORATORIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00003978AM24
RA File Number	318304000162 AM17
Licence No and Date	3110066602/28/02/2017
Norms Committee Decision: The committee has considered the case of the firm as per agenda and it has been observed that name of import item has already been corrected in the Meeting No. 05/AM20 dated 02.08.2019. Therefore, the committee decided to withdraw the application of the firm. The firm may also check the Minutes of the Meeting dated 02.08.2019 uploaded in the DGFT website Portal.	

Case No.	22 / NC/3/MEET/Aug/202324/11													
Case Status	Case Approved													
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023													
HQ File Number	HQRNORM REVIW00001053AM24													
RA File Number	039404000115 AM18													
Licence No and Date	0310813394/18/05/2017													
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:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>N-Methyl Pyrrolidone (Purity Minimum 99.8%, Moisture Less Than 1000 PPM)</td><td>1 kg.</td><td>1</td><td>N-Methyl Pyrrolidone (Purity Maximum 86.27%, Moisture 5% to 7%)</td><td>1.23 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	N-Methyl Pyrrolidone (Purity Minimum 99.8%, Moisture Less Than 1000 PPM)	1 kg.	1	N-Methyl Pyrrolidone (Purity Maximum 86.27%, Moisture 5% to 7%)	1.23 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
N-Methyl Pyrrolidone (Purity Minimum 99.8%, Moisture Less Than 1000 PPM)	1 kg.	1	N-Methyl Pyrrolidone (Purity Maximum 86.27%, Moisture 5% to 7%)	1.23 kg.										

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

Case No.	23 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00005839AM23
RA File Number	039404000733 AM18
Licence No and Date	0310817950/20/12/2017

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.
ACETONITRILE (Purity minimum 99.9%)	1.0 MT	1	ACETONITRILE (LOW PURITY) (Purity 98%)	1.19 MT

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

Case No.	24 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	SIDDHARTH CARBOCHEM PRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000275AM24
RA File Number	039504000992 AM18
Licence No and Date	0310819448/28/02/2018

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.
METHYL SALICYLATE (MIN 99 PERCENT) (PHENOL FREE)	1 kg.	1	SALICYLIC ACID	1.1715 kg.
		2	METHANOL	0.244 kg.

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

Case No.	25 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000299AM24
RA File Number	039404000160 AM19
Licence No and Date	0310822659/27/07/2018
Norms Committee Decision: The committee has considered the case of the firm as per agenda and it has been observed that the case of the firm had already been approved in its meeting No.NC/3/MEET/Jul/20202324/09 dated 28/07/2023 (Manual Case). Therefore, the committee decided to withdraw the application of the firm. The firm may also check the Minutes of the Meeting dated 28/07/2023 uploaded in the DGFT website Portal.	

Case No.	26 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000300AM24
RA File Number	039404000126 AM19
Licence No and Date	0310822660/27/07/2018
Norms Committee Decision: The committee has considered the case of the firm as per agenda and it has been observed that the case of the firm had already been approved in its meeting No.NC/3/MEET/Jul/20202324/09 dated 28/07/2023 (Manual Case). Therefore, the committee decided to withdraw the application of the firm. The firm may also check the Minutes of the Meeting dated 28/07/2023 uploaded in the DGFT website Portal.	

Case No.	27 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	INDO AMINES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023													
HQ File Number	HQRNORM REVIW00001307AM24													
RA File Number	039404000336 AM19													
Licence No and Date	0310822662/27/07/2018													
Norms Committee Decision:														
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-														
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>N METHYL MORPHOLINE OXIDE 50% OR IAL NMMO 50%</td> <td>1 kg.</td> <td>1</td> <td>MORPHOLINE</td> <td>0.46 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	N METHYL MORPHOLINE OXIDE 50% OR IAL NMMO 50%	1 kg.	1	MORPHOLINE	0.46 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
N METHYL MORPHOLINE OXIDE 50% OR IAL NMMO 50%	1 kg.	1	MORPHOLINE	0.46 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	28 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000298AM24
RA File Number	039404000142 AM19
Licence No and Date	0310822704/30/07/2018
Norms Committee Decision:	
The committee has considered the case of the firm as per agenda and it has been observed that the case of the firm had already been approved in its meeting No.NC/3/MEET/Jul/20202324/09 dated 28/07/2023 (Manual Case) . Therefore, the committee decided to withdraw the application of the firm. The firm may also check the Minutes of the Meeting dated 28/07/2023 uploaded in the DGFT website Portal.	

Case No.	29 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000301AM24
RA File Number	039404000141 AM19
Licence No and Date	0310822729/31/07/2018
Norms Committee Decision:	

The committee has considered the case of the firm as per agenda and it has been observed that the case of the firm had already been approved in its meeting **No.NC/3/MEET/Jul/20202324/09 dated 28/07/2023 (Manual Case)**. Therefore, the committee decided to withdraw the application of the firm. The firm may also check the Minutes of the Meeting dated 28/07/2023 uploaded in the DGFT website Portal.

Case No.	30 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000302AM24
RA File Number	039404000158 AM19
Licence No and Date	0310822734/31/07/2018
Norms Committee Decision:	
The committee has considered the case of the firm as per agenda and it has been observed that the case of the firm had already been approved in its meeting No.NC/3/MEET/Jul/20202324/09 dated 28/07/2023 (Manual Case) . Therefore, the committee decided to withdraw the application of the firm. The firm may also check the Minutes of the Meeting dated 28/07/2023 uploaded in the DGFT website Portal.	

Case No.	31 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000304AM24
RA File Number	039404000162 AM19
Licence No and Date	0310822732/31/07/2018
Norms Committee Decision:	
The committee has considered the case of the firm as per agenda and it has been observed that the case of the firm had already been approved in its meeting No.NC/3/MEET/Jul/20202324/09 dated 28/07/2023 (Manual Case) . Therefore, the committee decided to withdraw the application of the firm. The firm may also check the Minutes of the Meeting dated 28/07/2023 uploaded in the DGFT website Portal.	

Case No.	32 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
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 request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-

Justification of wastage at each stage of reaction with yield.

Case No.	33 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00001047AM24
RA File Number	039404000403 AM19
Licence No and Date	0310823513/04/09/2018

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.
N-Methyl Pyrrolidone (Purity Minimum 99.8%, Moisture Less Than 1000 PPM)	1 kg.	1	N-Methyl Pyrrolidone (Purity Maximum 86.27%, Moisture 5% to 7%)	1.23 kg.

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

Case No.	34 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000481AM24
RA File Number	039404000506 AM19
Licence No and Date	0310823810/18/09/2018

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/Mar/202223/22** dated **24/03/2023** against advance authorization **No.0310839173** dated **28/10/2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Norfloxacin	1 kg.	1	2,4 Dichloro-5-Fluoro Acetophenone(DCFA)	1.123 kg.
		2	Dimethyl Carbonate	1.010 kg.
		3	Sodium Hydride	0.289 kg.
		4	Toluene	0.800 kg.
		5	Acetic Acid	0.289 kg.
		6	Dimethyl Sulphate	0.670 kg.
		7	Dimethyl Formamide	0.500 kg.
		8	Mono Ethyl Amine (70%)	0.557 kg.
		9	Caustic Flakes	0.410 kg.
		10	Sulfuric Acid	Not Importable item
		11	Methanol	1.20 kg.

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

Case No.	35 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00002992AM24
RA File Number	039404000699 AM19
Licence No and Date	0310824906/05/11/2018
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.
Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray / Dymista Nasal Spray (Pack 120MD)(Each Spray delivers: Azelastine Hydrochloride BP 137mcg Fluticasone Propionate 50mcg)	1 Number	1	Azelastine Hydrochloride	16.44 mg.
		2	Fluticasone Propionate	6.00 mg.
		3	140 mcl pumps	Net to Net
		4	25ml USP type 1 amber glass vial	Net+1%
		5	Nasal actuator	Net to Net

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

Case No.	36 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	LUPIN LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00001950AM24
RA File Number	039504000814 AM19
Licence No and Date	0310825247/27/11/2018
Norms Committee Decision: The application of the firm was considered on the basis of agenda and the committee has observed that case of the firm comes under para 4.18 (Non-Infringing process) which does not require approval of NC. However, the Norms of the said item had inadvertently fixed by the Committee in its meeting No. 3/82-ALC4/2019 dated 05.07.2019. Therefore, the committee decided to withdraw the application of the firm and the decision which is taken in the meeting dated 05.07.2019 may also be withdrawn. RA concerned may take further necessary action under para 4.18 of HBP as per the above decision of NC.	

Case No.	37 / NC/3/MEET/Aug/202324/11
Case Status	Case Rejected
Party Name	ROYAL PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000092AM24
RA File Number	039504000945 AM19
Licence No and	0310825646/13/12/2018

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

Case No.	38 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	LUPIN LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00001951AM24
RA File Number	039504001008 AM19
Licence No and Date	0310826059/01/01/2019
Norms Committee Decision: The application of the firm was considered on the basis of agenda and the committee has observed that case of the firm comes under para 4.18 (Non-Infringing process) which does not require approval of NC. However, the Norms of the said item had inadvertently fixed by the Committee in its meeting No. 15/82-ALC4/2018 dated 22.03.2019. Therefore, the committee decided to withdraw the application of the firm and the decision which is taken in the meeting dated 22.03.2019 may also be withdrawn. RA concerned may take further necessary action under para 4.18 of HBP as per the above decision of NC.	

Case No.	39 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000817AM24
RA File Number	082404000026 AM20
Licence No and Date	0810145127/30/04/2019
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Complete chemistry giving molecular weight of reactant and products, with stage wise yield (also over all yield) 2. Justification of wastage at each stage of reaction.	

Case No.	40 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00002204AM23
RA File Number	052304000048 AM20
Licence No and Date	0510410475/03/05/2019
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	41 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	NOVEL NUTRIENTSS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00001063AM24
RA File Number	072404000056 AM20
Licence No and Date	0710115041/11/06/2019
Norms Committee Decision:	
The committee considered the request of the firm for review of ad-hoc norms and it has been observed that the details in reply of DL have not given by the firm. Thereafter, it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith following information / documents:- 1. Copy of approval from Food & Drugs Administration (FDA) for the export product. 2. COA for import item from foreign supplier.	

Case No.	42 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	MENTHA AND ALLIED PRODUCTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	018205000763AM20
RA File Number	052404000375 AM20
Licence No and Date	0510412231/23/10/2019
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.
ORANGE ALDEHYDE	92.27 kg.	1	ORANGE OIL	96.88 kg.
D LIMONENE	11764.00 kg.	1	ORANGE OIL	12352.20 kg.
ORANGE OIL 10X	1291.73 kg.	1	ORANGE OIL	1356.31 kg.

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

Case No.	43 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00006311AM23
RA File Number	039504000760 AM20
Licence No and Date	0310832692/11/11/2019
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	44 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	TADIMETY AROMATICS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM REVIW00000940AM24			
RA File Number	072404000229 AM20			
Licence No and Date	0710115939/27/12/2019			
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:-				

(Trichloro-Phenyl Methyl Corbiny Acetate)				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	45 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	REFLUX PHARMACEUTICALS
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00001517AM24
RA File Number	NA
Licence No and Date	0310833815/01/01/2020
Norms Committee Decision:	
The committee considered the request of the firm and observed that the firm has filed dual application on same license number as mentioned at case No.46, therefore, the committee has decided to withdraw the application of the firm.	

Case No.	46 / NC/3/MEET/Aug/202324/11													
Case Status	Case Approved													
Party Name	REFLUX PHARMACEUTICALS													
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023													
HQ File Number	HQRNORM REVIW00002730AM24													
RA File Number	039504000931 AM20													
Licence No and Date	0310833815/01/01/2020													
Norms Committee Decision:														
The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty.</th></tr><tr><td rowspan="2">TOLFENAMIC ACID(B ULK DRUG)</td><td rowspan="2">1 kg.</td><td>1</td><td>ORTHO CHLOROBENZOIC ACID</td><td>0.75 kg.</td></tr><tr><td>2</td><td>3-CHLORO-2-METHYLANILINE</td><td>0.67 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	TOLFENAMIC ACID(B ULK DRUG)	1 kg.	1	ORTHO CHLOROBENZOIC ACID	0.75 kg.	2	3-CHLORO-2-METHYLANILINE	0.67 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
TOLFENAMIC ACID(B ULK DRUG)	1 kg.	1	ORTHO CHLOROBENZOIC ACID	0.75 kg.										
		2	3-CHLORO-2-METHYLANILINE	0.67 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	47 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000303AM24
RA File Number	039404000888 AM20
Licence No and Date	0310834332/20/01/2020
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	48 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	AURA LIFECARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00001012AM24
RA File Number	342404000323 AM20
Licence No and Date	3410045804/23/01/2020
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Copy of Drugs Manufacturing License (DML) showing approved composition for each export items. 2. Why percentage <i>Dextrose</i> content is different in different pack size?	

Case No.	49 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000113AM24
RA File Number	318304000140 AM20
Licence No and Date	3110067673/06/02/2020
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-	

Export Product	Qty.	Sl. No.	Import Items	Qty.
Acetyl Anisole (4 Methoxy Acetophenone)	1 kg.	1	Phenol	0.74 kg.
		2	Methanol	0.283 kg.
		3	Acetic Anhydride PURITY 99%	0.755 kg.

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

Case No.	50 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000946AM24
RA File Number	072404000276 AM20
Licence No and Date	0710116142/18/02/2020

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.
Rosecrystals Ex Benzaldehyde (Trichloro-Phenyl Methyl Corbinyl Acetate)	1 kg.	1	Benzaldehyde	0.465 kg.

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

Case No.	51 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00005394AM23
RA File Number	052404000004 AM21

Licence No and Date	0510414006/16/04/2020			
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.
CEFEPIME FOR INJECTION	1 kg.	1	CEFEPIME HCL (NON STERILE)	0.655 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	52 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM REVIW00000929AM24			
RA File Number	092404000059 AM21			
Licence No and Date	0910068716/01/05/2020			
Norms Committee Decision:				
The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to ratify ad-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.
FAVIPIRAVIR	1 kg.	1	6-bromo-3-hydroxy pyrazine-2-carboxamide	2.32 Kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	53 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM REVIW00000114AM24			

RA File Number	318304000006 AM21																			
Licence No and Date	3110067737/18/05/2020																			
Norms Committee Decision:																				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-																				
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td rowspan="3">Acetyl Anisole (4 Methoxy Acetophenone)</td><td rowspan="3">1 kg.</td><td>1</td><td>Phenol</td><td>0.74 kg.</td></tr><tr><td>2</td><td>Methanol</td><td>0.283 kg.</td></tr><tr><td>3</td><td>Acetic Anhydride PURITY 99%</td><td>0.755 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Acetyl Anisole (4 Methoxy Acetophenone)	1 kg.	1	Phenol	0.74 kg.	2	Methanol	0.283 kg.	3	Acetic Anhydride PURITY 99%	0.755 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.																
Acetyl Anisole (4 Methoxy Acetophenone)	1 kg.	1	Phenol	0.74 kg.																
		2	Methanol	0.283 kg.																
		3	Acetic Anhydride PURITY 99%	0.755 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	54 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	NOVEL NUTRIENTSS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00001058AM24
RA File Number	072404000038 AM21
Licence No and Date	0710116503/26/05/2020
Norms Committee Decision:	
The committee considered the request of the firm for review of ad-hoc norms and it has been observed that the details in reply of DL have not given by the firm. Thereafter, it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case alongwith following information / documents:-	
1. Copy of approval from Food & Drugs Administration (FDA) for the export product.	
2. COA for import item from foreign supplier.	

Case No.	55 / NC/3/MEET/Aug/202324/11			
Case Status	Case Deferred			
Party Name	CLARIANT INDIA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			

HQ File Number	018205001343AM21
RA File Number	039404000110 AM21
Licence No and Date	0310836469/01/06/2020
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.	56 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BROOKS LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004249AM24
RA File Number	302404000010 AM21
Licence No and Date	3010105213/02/06/2020
Norms Committee Decision: The case is under consideration for want of comments of TE	

Case No.	57 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000118AM24
RA File Number	318304000011 AM21
Licence No and Date	3110067749/03/06/2020
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- i. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. ii. End use of final product	

Case No.	58 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023

HQ File Number	HQRNORM REVIW00000931AM24													
RA File Number	092404000262 AM21													
Licence No and Date	0910069046/17/08/2020													
Norms Committee Decision:														
The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to ratify ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>FAVIPIRAVIR</td><td>1 kg.</td><td>1</td><td>6-bromo-3-hydroxy pyrazine-2-carboxamide</td><td>2.32 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	FAVIPIRAVIR	1 kg.	1	6-bromo-3-hydroxy pyrazine-2-carboxamide	2.32 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
FAVIPIRAVIR	1 kg.	1	6-bromo-3-hydroxy pyrazine-2-carboxamide	2.32 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	59 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	AURA LIFECARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00001123AM24
RA File Number	342404000133 AM21
Licence No and Date	3410046298/18/08/2020
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
i. Copy of Drugs Manufacturing License (DML) showing approved composition for each export items.	
ii. Why percentage <i>Dextrose</i> content is different in different pack size?	

Case No.	60 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00005055AM23
RA File Number	092404000282 AM21
Licence No and Date	0910069242/22/09/2020
Norms Committee Decision:	

The case is under consideration for want of comments of TE

Case No.	61 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	SRI CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004706AM24
RA File Number	042404000109 AM21
Licence No and Date	0410167147/07/10/2020

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.
EN DEFOAM-A (Monovalent Defoamer Alcohol base)	1 kg	1	POLY ETHYLENE GLYCOL BUTYL ETHER	0.997 kg.

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

Case No.	62 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	SMILAX LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004228AM24
RA File Number	092404000358 AM21
Licence No and Date	0910069312/08/10/2020

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
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GURATIMOD	1 kg.	1	4-Chloro-3-Nitro Anisole	1.87 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	63 / NC/3/MEET/Aug/202324/11
Case Status	Case Rejected
Party Name	ROYAL PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000094AM24
RA File Number	039504000439 AM21
Licence No and Date	0310838908/15/10/2020
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.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	64 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004153AM23
RA File Number	039404000571 AM21
Licence No and Date	0310839148/27/10/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	65 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00007179AM23
RA File Number	018205001835 AM21
Licence No and Date	3410046524/05/11/2020

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/Feb/202223/20 dated 24/02/2023** against advance authorization **No. 3410045200 dated 10/06/2019**, 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.
Gamma Nonalactone or Aldehyde C18	1 kg.	1	Hexyl Alcohol or N-Hexanol	1.36 kg.
		2	Acrylic Acid	0.96 kg.
		3	Di-tert Butyl Peroxide	0.229 kg.

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

Case No.	66 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00034564AM21
RA File Number	05AA04017512 AM21
Licence No and Date	0511000078/09/12/2020

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.
OXALIPLATIN(USP)	1 kg.	1	Platinum Sponge Powder	0.85 kg.
		2	(1R,2R)-(-)-1,2-Diamino Cyclo Hexane.	0.49 kg.

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

Case No.	67 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000489AM24
RA File Number	03AA04019523 AM21
Licence No and Date	0311001089/20/01/2021

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/Mar/202223/22** dated **24/03/2023** against advance authorization **No.0310839173** dated **28/10/2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Norfloxacin(Norflo)	1 kg.	1	2,4 Dichloro-5-Fluoro Acetophenone(DCFA)	1.123 kg.
		2	Dimethyl Carbonate	1.010 kg.
		3	Dimethyl Formamide	0.50 kg.
		4	Mono Ethyl Amine(70%)	0.557 kg.
		5	Piperazine Anhydrous	0.665 kg.
		6	Methanol	1.20 kg.

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

Case No.	68 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	REFLUX PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00001513AM24
RA File Number	NA
Licence No and Date	0311001445/03/02/2021

Norms Committee Decision:

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

Case No.	69 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004407AM24
RA File Number	03AA04023340 AM21
Licence No and Date	0311001698/16/02/2021

Norms Committee Decision:

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

No justification is given for the above reasons of rejections. The firm has applied Brimonidine whereas DML shows Brimonidite Tartrate in the approved composition.

Case No.	70 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00101696AM21
RA File Number	09AA04005325 AM21
Licence No and Date	0911000494/11/03/2021

Norms Committee Decision:

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

Case No.	71 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	RECKITT BENCKISER HEALTHCARE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00103707AM21
RA File Number	05AA04039234 AM21
Licence No and Date	0511001736/15/03/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
Corn Foam Cushion	280000.0 Numbers	1	LACQUERED DUAL LAYER	1.05 SQM/SQM content in export.
		2	TECHNOMELT PSM 551 DERMA-TEK	1.05 kg./kg. content in export.
		3	RELEASE PAPER 2PE160/ 11 WH	1.05 SQM/SQM content in export.
Soft Corn Cushions	20000.0 Numbers	4	LACQUERED DUAL LAYER	1.05 SQM/SQM content in export.
		5	TECHNOMELT PSM 551 DERMA-TEK	1.05 kg./kg. content in export.
		6	RELEASE PAPER 2PE160/ 11 WH	1.05 SQM/SQM content in export.
CALLUS FOAM CUSHION	50000.0 Numbers	7	LACQUERED DUAL LAYER	1.05 SQM/SQM content in export.
		8	TECHNOMELT PSM 551 DERMA-TEK	1.05 kg./kg. content in export.
		9	RELEASE PAPER 2PE160/ 11 WH	1.05 SQM/SQM content in export.

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

Case No.	72 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BROOKS LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004240AM24
RA File Number	30AA04005114 AM21

Licence No and Date	3011000438/25/03/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	73 / NC/3/MEET/Aug/202324/11													
Case Status	Case Approved													
Party Name	AURORIUM INDIA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023													
HQ File Number	HQRNORM REVIW00002075AM24													
RA File Number	03AA04032376 AM21													
Licence No and Date	0311002851/31/03/2021													
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:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>4 Cyanopyridine</td><td>1 kg</td><td>1</td><td>Gamma Picoline</td><td>1.098 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	4 Cyanopyridine	1 kg	1	Gamma Picoline	1.098 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
4 Cyanopyridine	1 kg	1	Gamma Picoline	1.098 kg.										
RA concerned may take further necessary action as per the above decision of NC.														

Case No.	74 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	CLARIANT INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004498AM24
RA File Number	03AA04009823 AM22
Licence No and Date	0311003530/04/05/2021
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.	

Case No.	75 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			

Party Name	RUMIT LIFE CARE														
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023														
HQ File Number	HQRNORM REVIW00000680AM24														
RA File Number	03AA04021934 AM22														
Licence No and Date	0311004279/03/06/2021														
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:-															
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>Betamethasone Dipropionate (Net Content Betamethasone 17 Propionate BP/EP/USP = 100 kgs)(Betamethasone Dipropionate (Net Content Betamethasone 17 Propionate BP/EP/USP = 100 kgs))</td><td>1 kg.</td><td>1</td><td>Betamethasone 17 Propionate</td><td>0.94 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty.	Betamethasone Dipropionate (Net Content Betamethasone 17 Propionate BP/EP/USP = 100 kgs)(Betamethasone Dipropionate (Net Content Betamethasone 17 Propionate BP/EP/USP = 100 kgs))	1 kg.	1	Betamethasone 17 Propionate	0.94 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.											
Betamethasone Dipropionate (Net Content Betamethasone 17 Propionate BP/EP/USP = 100 kgs)(Betamethasone Dipropionate (Net Content Betamethasone 17 Propionate BP/EP/USP = 100 kgs))	1 kg.	1	Betamethasone 17 Propionate	0.94 kg.											
RA concerned may take further necessary action as per above decision of NC.															

Case No.	76 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004760AM24
RA File Number	03AA04021964 AM22
Licence No and Date	0311004323/04/06/2021
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
COA of import item from foreign supplier showing actual potency of import.	

Case No.	77 / NC/3/MEET/Aug/202324/11			
Case Status	Case Deferred			
Party Name	SWISS PARENTERALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM REVIW00003403AM23			
RA File Number	08AA04007143 AM22			

Licence No and Date	0811001742/15/06/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	78 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	ORGANIC INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
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 NC-6 for obtaining their comments.	

Case No.	79 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	CUTCH OIL AND ALLIED INDUSTRIES 1949 PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000966AM24
RA File Number	02AA04007136 AM22
Licence No and Date	0211000893/05/07/2021
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. Certificate of Analysis (CoA) report of both import and export items, indicating composition and moisture content. 2. Justification for 27% wastage of import item.	

Case No.	80 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00138116AM22
RA File Number	26AA04002063 AM22
Licence No and Date	2611000198/13/07/2021
Norms Committee Decision:	

The case is under consideration for want of comments of TE

Case No.	81 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	DIAMINES AND CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00145203AM22
RA File Number	34AA04005573 AM22
Licence No and Date	3411000885/22/07/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	82 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SYNOKEM PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00147457AM22
RA File Number	05AA04059070 AM22
Licence No and Date	0511003826/26/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed the following based on the documents furnished by the firm:- 1. Export item is shown as 20 mg. Tube which appears to be wrong in view of DML received. 2. Description of import item is confusing in view of CoA now received. In view of the above, the committee has decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	83 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SUNDYOTA NUMANDIS PROBIOCEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
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 was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	84 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00005936AM23
RA File Number	34AA04006527 AM22
Licence No and Date	3411000984/17/08/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	85 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00006174AM23
RA File Number	NA
Licence No and Date	3411000984/17/08/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	86 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00170502AM22
RA File Number	08AA04022482 AM22
Licence No and Date	0811002393/25/08/2021
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	87 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00001335AM24
RA File Number	31AA04025740 AM22
Licence No and Date	3111000548/26/08/2021

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.
DI ETHYLENE TRI AMINE (ORGANIC CHEMICALS)	1 kg.	1	MONOETHANOLAMINE	1.184 kg.
		2	AMMONIAANHYDROUS	0.165 kg.

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

Case No.	88 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00178977AM22
RA File Number	08AA04026034 AM22
Licence No and Date	0811002528/07/09/2021

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.
METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS:	1 Number Vial	1	METHOTREXATE EP / BP / IP / USP / PH. EUR.	61.87 mg/vial

METHOTREXATE PH. EUR. 25MG)			(Moisture and Residual Solvents content not less than 12.49% in API)	
METHOTREXATE INJECTION BP 100MG/ML [5 ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100 MG)	1 Number Vial	2	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	618.70 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL](EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)	1 Number Vial	3	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1237.39 mg/vial
METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL](EACH ML CONTAINS: METHOTREXATE USP 25MG)	1 Number Vial	4	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	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. (Moisture and Residual Solvents content not less than 12.49% in API)	590.57 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	6	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1181.15 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 32.500 KGS.])	1 Number Vial	7	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	5737.00 mg/vial
RA concerned may take further necessary action as per above decision of NC.				

Case No.	89 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004715AM24
RA File Number	05AA04071036 AM22
Licence No and Date	0511004601/08/09/2021
Norms Committee Decision:	

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

- i. **Legible copy of chemical reaction sheet.**
- ii. **Percentage of solvents recovered & commercial value of spent solvent.**
- iii. **In chemical reaction Trifluoro Phenyl Chloride is used while import is Trifluoro Phenyl Fluoride.**

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.	90 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	DIAMINES AND CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00184161AM22
RA File Number	34AA04007354 AM22
Licence No and Date	3411001111/15/09/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	91 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	CUCKOS PHARMACEUTICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00184568AM22
RA File Number	33AA04006480 AM22
Licence No and Date	3311000430/15/09/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	92 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00187904AM22
RA File Number	08AA04029099 AM22
Licence No and Date	0811002644/20/09/2021
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.
METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	1	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	61.87 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [5 ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100 MG)	1 Number Vial	2	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	618.70 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL](EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)	1 Number Vial	3	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1237.39 mg/vial
METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL](EACH ML CONTAINS: METHOTREXATE USP 25MG)	1 Number Vial	4	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	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. (Moisture and Residual Solvents content not less than 12.49% in API)	590.57 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	6	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1181.15 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 32.500 KGS.])	1 Number Vial	7	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	5737.00 mg/vial

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

Case No.	93 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	ASOJ SOFT CAPS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00190578AM22
RA File Number	34AA04007816 AM22
Licence No and Date	3411001148/22/09/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	94 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00195372AM22
RA File Number	34AA04006808 AM22
Licence No and Date	3411001180/27/09/2021
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.	95 / NC/3/MEET/Aug/202324/11														
Case Status	Case Approved														
Party Name	INTAS PHARMACEUTICALS LIMITED														
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023														
HQ File Number	HQRNORM REVIW00001473AM23														
RA File Number	08AA04029213 AM22														
Licence No and Date	0811002696/27/09/2021														
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:-															
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>TOPOTECAN INJECTION 1 MG/ML, 1 ML VIAL(EACH ML CONTAINS TOPOTECAN HYDROCHLORIDE EQ. TO TOPOTECAN</td><td>1 Number</td><td>1</td><td>TOPOTECAN HYDROCHLORIDE (Water and Residual solvents content not</td><td>1.313 mg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty.	TOPOTECAN INJECTION 1 MG/ML, 1 ML VIAL(EACH ML CONTAINS TOPOTECAN HYDROCHLORIDE EQ. TO TOPOTECAN	1 Number	1	TOPOTECAN HYDROCHLORIDE (Water and Residual solvents content not	1.313 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty.											
TOPOTECAN INJECTION 1 MG/ML, 1 ML VIAL(EACH ML CONTAINS TOPOTECAN HYDROCHLORIDE EQ. TO TOPOTECAN	1 Number	1	TOPOTECAN HYDROCHLORIDE (Water and Residual solvents content not	1.313 mg.											

1MG)			less than 9.0% in the API)	
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 98.000 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.	96 / NC/3/MEET/Aug/202324/11													
Case Status	Case Approved													
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023													
HQ File Number	HQRNORM APPLY 00205042AM22													
RA File Number	03AA040108575 AM22													
Licence No and Date	0311007542/07/10/2021													
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:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>Isobornyl Cyclohexanol</td><td>1 kg.</td><td>1</td><td>Gum Turpentine Oil</td><td>1.582 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Isobornyl Cyclohexanol	1 kg.	1	Gum Turpentine Oil	1.582 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
Isobornyl Cyclohexanol	1 kg.	1	Gum Turpentine Oil	1.582 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	97 / NC/3/MEET/Aug/202324/11			
Case Status	Case Deferred			
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			

HQ File Number	HQRNORM APPLY 00212058AM22
RA File Number	03AA040109332 AM22
Licence No and Date	0311007711/14/10/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	98 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00001474AM23
RA File Number	08AA04033170 AM22
Licence No and Date	0811002920/20/10/2021

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.
METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	1	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	61.87 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [5 ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100 MG)	1 Number Vial	2	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	618.70 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL](EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)	1 Number Vial	3	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1237.39 mg/vial
METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL](EACH ML CONTAINS: METHOTREXATE USP 25MG)	1 Number Vial	4	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	306.867 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [20ML VIAL](EACH ML CONTAINS:	1 Number Vial	5	METHOTREXATE EP / BP / IP / USP / PH. EUR.	590.57 mg/vial

METHOTREXATE PH. EUR. 25MG)			(Moisture and Residual Solvents content not less than 12.49% in API)	
METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	6	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1181.15 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 32.500 KGS.]	1 Number Vial	7	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	5737.00 mg/vial

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

Case No.	99 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
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 it was decided to call for following information/documents from the firm:- 1. Complete chemistry, molecular weight, percentage yields on molar basis. 2. Past production/consumption certificate certified by CA.	

Case No.	100 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
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 it was decided to call for following information/documents from the firm:-	

- i. **Complete chemistry, molecular weight, percentage yields on molar basis.**
 ii. **Past production/consumption certificate certified by CA.**

Case No.	101 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	THEMIS NUTRITIONALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00221695AM22
RA File Number	03AA040108212 AM22
Licence No and Date	0311007847/22/10/2021

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.
Enalapril 5 mg Tablets(Enalapril)	1 Number Tablet	1	ENALAPRIL MALEATE EP	5.10 mg/Tablet
Enalapril 10 mg Tablets(Enalapril)	1 Number Tablet	2	ENALAPRIL MALEATE EP	10.2 mg/Tablet
Enalapril 20 mg Tablets(Enalapril)	1 Number Tablet	3	ENALAPRIL MALEATE EP	20.4 mg/Tablet

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

Case No.	102 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00226905AM22
RA File Number	05AA04094141 AM22
Licence No and Date	0511005704/26/10/2021

Norms Committee Decision:

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

Case No.	103 / NC/3/MEET/Aug/202324/11
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Case Status	Case Deferred
Party Name	BHARAT PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00239596AM22
RA File Number	34AA04008748 AM22
Licence No and Date	3411001363/02/11/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	104 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00253243AM22
RA File Number	34AA04009242 AM22
Licence No and Date	3411001396/15/11/2021

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.
Ointment(Clobetasol Propionate Ointment USP 0.05% 15 gm (net content of active ingredients 187.50 gm.))	1 Number	1	CLOBETASOL PROPIONATE USP (MICRONIZED)	7.65 mg/pack
Ointment(Clobetasol Propionate Ointment USP 0.05% 30 gm (net content of active ingredients 225.00 gm.))	1 Number	2	CLOBETASOL PROPIONATE USP (MICRONIZED)	15.30 mg/pack
Ointment(Clobetasol Propionate Ointment USP 0.05% 45 gm (net content of active ingredients 114.75 gm.))	1 Number	3	CLOBETASOL PROPIONATE USP (MICRONIZED)	22.95 mg/pack
Ointment(Clobetasol Propionate Ointment USP 0.05% 60 gm (net content of active ingredients 900.00 gm.))	1 Number	4	CLOBETASOL PROPIONATE USP (MICRONIZED)	30.60 mg/pack
Foam(Clobetasol Propionate Foam USP 0.05% 50gm. (net content of active	1 Number	5	CLOBETASOL PROPIONATE USP (MICRONIZED)	25.50 mg/pack

ingredients 475.00 gm.))				
Foam(Clobetasol Propionate Foam USP 0.05% 100 gm. (net content of active ingredients 550.00 gm.))	1 Number	6	CLOBETASOL PROPIONATE USP (MICRONIZED)	51.00 mg/pack

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

Case No.	105 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00261092AM22
RA File Number	09AA04016734 AM22
Licence No and Date	0911001888/22/11/2021
Norms Committee Decision: The Committee considered the 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.	106 / NC/3/MEET/Aug/202324/11																
Case Status	Case Approved																
Party Name	FRESENIUS KABI ONCOLOGY LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023																
HQ File Number	HQRNORM APPLY 00262423AM22																
RA File Number	05AA04098088 AM22																
Licence No and Date	0511006367/23/11/2021																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty.</th></tr><tr><td rowspan="2">Docetaxel Trihydrate.(Anti cancer bulk drug)</td><td rowspan="2">1 kg</td><td>1</td><td>Taxus Baccatta Leaves</td><td>1340 kg</td></tr><tr><td>2</td><td>DSC -9 [4S,5R)-2-(4-methoxyphenyl)-N-t-boc-phenyl-</td><td>0.888 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Docetaxel Trihydrate.(Anti cancer bulk drug)	1 kg	1	Taxus Baccatta Leaves	1340 kg	2	DSC -9 [4S,5R)-2-(4-methoxyphenyl)-N-t-boc-phenyl-	0.888 kg
Export Product	Qty.	Sl. No.	Import Items	Qty.													
Docetaxel Trihydrate.(Anti cancer bulk drug)	1 kg	1	Taxus Baccatta Leaves	1340 kg													
		2	DSC -9 [4S,5R)-2-(4-methoxyphenyl)-N-t-boc-phenyl-	0.888 kg													

			oxazolidine-5-carboxylic acid]	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	107 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	LAZERHEAD LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00266328AM22
RA File Number	09AA04012424 AM22
Licence No and Date	0911001950/26/11/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	108 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00272724AM22
RA File Number	03AA040127775 AM22
Licence No and Date	0311009114/02/12/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	109 / NC/3/MEET/Aug/202324/11
Case Status	Case Rejected
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000792AM24
RA File Number	07AA04040783 AM22
Licence No and Date	0711002512/02/12/2021
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.

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

Case No.	110 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004710AM24
RA File Number	03AA040124486 AM22
Licence No and Date	0311009090/02/12/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	111 / NC/3/MEET/Aug/202324/11																
Case Status	Case Approved																
Party Name	RAKSHIT PHARMACEUTICALS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023																
HQ File Number	HQRNORM APPLY 00276086AM22																
RA File Number	09AA04016769 AM22																
Licence No and Date	0911002001/06/12/2021																
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/Apr/202324/1 dated 28.04.2023 against advance authorization No. 0911004282 dated 09.01.2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty.</th></tr><tr><td rowspan="3">MYCOPHENOLATE SODIUM(SOLID)</td><td rowspan="3">1 Kg</td><td>1</td><td>Mycophenolic Acid</td><td>0.90 kg</td></tr><tr><td>2</td><td>Toluene</td><td>0.66 kg</td></tr><tr><td>3</td><td>Methanol</td><td>0.70 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	MYCOPHENOLATE SODIUM(SOLID)	1 Kg	1	Mycophenolic Acid	0.90 kg	2	Toluene	0.66 kg	3	Methanol	0.70 kg
Export Product	Qty.	Sl. No.	Import Items	Qty.													
MYCOPHENOLATE SODIUM(SOLID)	1 Kg	1	Mycophenolic Acid	0.90 kg													
		2	Toluene	0.66 kg													
		3	Methanol	0.70 kg													

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

Case No.	112 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00276997AM22
RA File Number	30AX04000001 AM22
Licence No and Date	3011001471/06/12/2021

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.
VINORELBINE SOLUTION FOR INJECTION (50MG/5ML)(1 ML OF SOLUTION CONTAINS: VINORELBINE TARTRATE , EQUIVALENT TO VINORELBINE 10MG EXCIPIENTS: TARTARIC ACID, WATER FOR INJECTION)	1450.0 Vials	1	VINORELBINE TARTRATE	100.05 gm.
VINORELBINE SOLUTION FOR INJECTION (10MG5ML)(1 ML OF SOLUTION CONTAINS: VINORELBINE TARTRATE , EQUIVALENT TO VINORELBINE 10MG EXCIPIENTS: TARTARIC ACID, WATER FOR INJECTION)	7250.0 Vials	2	VINORELBINE TARTRATE	100.05 gm.

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

Case No.	113 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	AURA PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00277561AM22
RA File Number	03AA040123116 AM22
Licence No and Date	0311009243/07/12/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
ARGYROL 0.5% / SILVER VITELLINATE NASAL DROPS 0.5 % w/v (EACH 10 ML CONTAINS 52 MG OF SILVER VITELLINATE)	1 Number	1	SILVER VITELLINATE	51.00 mg.
ARGYROL 1 % / SILVER VITELLINATE NASAL DROPS 1 % w/v (EACH 10 ML CONTAINS 104 MG OF SILVER VITELLINATE)	1 Number	2	SILVER VITELLINATE	102.00 mg

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

Case No.	114 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00277912AM22
RA File Number	05AA040108247 AM22
Licence No and Date	0511006681/07/12/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	115 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00289566AM22
RA File Number	34AX04000036 AM22
Licence No and Date	3411001553/17/12/2021
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.	116 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00289569AM22
RA File Number	34AX04000035 AM22
Licence No and Date	3411001554/17/12/2021
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.	117 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	NATCO PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004488AM24
RA File Number	09AX04000043 AM22
Licence No and Date	0911002121/21/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	118 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004714AM24
RA File Number	05AX04000086 AM22
Licence No and Date	0511007243/27/12/2021
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Percentage Recovery of Acetone & Toluene in the process. 2. Commercial value of Mix Solvent obtained in process.	

Case No.	119 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred

Party Name	CLARIANT INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004497AM24
RA File Number	03AX04000499 AM22
Licence No and Date	0311009919/30/12/2021
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.	120 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00324009AM22
RA File Number	03AX04000495 AM22
Licence No and Date	0311010688/19/01/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Quantity of Phenol recovered and its sale value in domestic market alongwith sales invoice.	

Case No.	121 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00007005AM23
RA File Number	34AX04000212 AM22
Licence No and Date	3411001750/04/02/2022
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.	122 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023

HQ File Number	HQRNORM REVIW00000257AM24
RA File Number	03AX04001590 AM22
Licence No and Date	0311013222/22/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	123 / NC/3/MEET/Aug/202324/11																
Case Status	Case Approved																
Party Name	SUNSHIELD CHEMICALS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023																
HQ File Number	HQRNORM APPLY 00000186AM23																
RA File Number	03AX04000112 AM23																
Licence No and Date	0311013797/11/04/2022																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td rowspan="2">SDPA (STYRENATED DI-PHENYLAMINE)</td><td rowspan="2">1 kg.</td><td>1</td><td>DI-PHENYLAMINE</td><td>0.515 kg.</td></tr><tr><td>2</td><td>STYRENE MONOMER</td><td>0.529 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	SDPA (STYRENATED DI-PHENYLAMINE)	1 kg.	1	DI-PHENYLAMINE	0.515 kg.	2	STYRENE MONOMER	0.529 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.													
SDPA (STYRENATED DI-PHENYLAMINE)	1 kg.	1	DI-PHENYLAMINE	0.515 kg.													
		2	STYRENE MONOMER	0.529 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	124 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005246AM23
RA File Number	NA
Licence No and Date	0711003752/20/04/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Apr/202324/1** dated **28/04/2023** against advance authorization **No.0711005991** dated **23/12/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
CAL - SUP TABLETS((CALCIUM CARBONATE 1250mg+ GLYCINE 535.7mg) (Glycine - 1000.000 KGS + Calcium - 1 2333.396 KGS) (No of Tabs - 1866716) USP/BP/EP)	1 Number	1	GLYCINE USP/BP/EP	537.7 mg/tablet
		2	CALCIUM CARBONATE DENSE BP/USP	1275 mg/tablet

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

Case No.	125 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00000501AM23
RA File Number	09AX04000388 AM22
Licence No and Date	0911002925/29/04/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	126 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00000815AM23
RA File Number	31AX04000039 AM23
Licence No and Date	3111001366/17/05/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty.
2,6 Xylidine	1 kg.	1	OCP 50 (Containing 38% Phenol and 58% Cresol)	1.4 kg
		2	Methanol	0.76 kg
		3	Katalco 71-5 F (Catalyst contains Fe ₂ O ₃ , Cr ₂ O ₃ , CuO&S)	0.004 kg.
		4	Catalyst {PD on alumina catalyst (pd content 0.4-0.5%)}	0.00161 kg.

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

Case No.	127 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00000944AM23
RA File Number	09AX04000145 AM23
Licence No and Date	0911003039/23/05/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	128 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00003358AM24
RA File Number	30AX04000065 AM23
Licence No and Date	3011002150/23/05/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	129 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	ALTA LABORATORIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00000980AM23
RA File Number	03AX04000822 AM23
Licence No and Date	0311014992/25/05/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	130 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00001002AM23
RA File Number	07AX04000209 AM23
Licence No and Date	0711004103/26/05/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	131 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004512AM24
RA File Number	03AX04000506 AM23
Licence No and Date	0311015097/30/05/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	132 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00001173AM23
RA File Number	03AX04001017 AM23
Licence No and Date	0311015227/03/06/2022
Norms Committee Decision:	

The committee considered the request of firm for fixation of ad-hoc norms and it has been observed that the firm has still not furnished the following items in reply to DL, the committee has decided to call for same from the firm:-

Production/Consumption data duly certified by GST.

Case No.	133 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	NATCO PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004490AM24
RA File Number	09AX04000174 AM23
Licence No and Date	0911003150/08/06/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	134 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	NASENSE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00001297AM23
RA File Number	09AX04000213 AM23
Licence No and Date	0911003160/09/06/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	135 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00002079AM24
RA File Number	03AX04001135 AM23
Licence No and Date	0311015463/13/06/2022
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-	

Export Product	Qty.	Sl. No.	Import Items	Qty.
PERINDOPRIL ERBUMINE	1 kg.	1	(S)-2-CARBOXY OCTAHYDROINDOLE	0.60 kg.
		2	1,1-CARBONYLDIIMIDAZOLE	0.64 kg.
		3	ACETIC ACID GLACIAL	0.48 kg.
		4	ACETONE	6.88 kg.
		5	ACETONITRILE	3.90 kg.
		6	ISOPROPYL ALCOHOL	1.97 kg.
		7	METHYLENE CHLORIDE (MDC)	6.15 kg.
		8	N-[(S)-1-CARBETHOXYBUTY](S)ALANINE	0.85 kg.

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

Case No.	136 / NC/3/MEET/Aug/202324/11
Case Status	Case Rejected
Party Name	ROYAL PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00006958AM23
RA File Number	03AX04001263 AM23
Licence No and Date	0311015473/13/06/2022
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	137 / NC/3/MEET/Aug/202324/11
Case Status	Case Rejected
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023

and Date	
HQ File Number	HQRNORM REVIW00000335AM24
RA File Number	07AX04000446 AM23
Licence No and Date	0711004428/28/06/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm has not furnished proper justification as per packing policy. Hence, the Committee decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	138 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00001745AM23
RA File Number	34AX04000259 AM23
Licence No and Date	3411002449/29/06/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	139 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00005934AM23
RA File Number	34AX04000311 AM23
Licence No and Date	3411002472/01/07/2022
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.	140 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	SAGA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00001849AM23
RA File Number	08AX04000569 AM23

Licence No and Date	0811005433/05/07/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty.
(Diosmin (600 mg)	1 Number	1	Diosmin (Assay by HPLC 90.58 %)	675.65 mg.
RA concerned may take further necessary action as per above decision of				

Case No.	141 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	HETERO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM APPLY 00002166AM23			
RA File Number	09AX04000298 AM23			
Licence No and Date	0911003371/20/07/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty.
(S)-TERT-BUTYL-3-OXO-1-PHENYLPROPYLCARBAMATE	1 kg	1	Malonic acid	4.46 kg.
		2	L (+) Tartaric acid	2.41 kg.
		3	2,2,6,6-tetramethyl piparidine-1-oxyl	0.27 kg.
		4	Thionyl Chloride	3.81 kg.
		5	Di Tert.Butyl Di Carbonate	1.57 kg.

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

Case No.	142 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00002091AM24
RA File Number	03AX04002253 AM23
Licence No and Date	0311016458/20/07/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
PERINDOPRIL ERBUMINE	1 kg.	1	(S)-2-CARBOXY OCTAHYDROINDOLE	0.60 kg.
		2	1,1-CARBONYLDIIMIDAZOLE	0.64 kg.
		3	ACETIC ACID GLACIAL	0.48 kg.
		4	ACETONE	6.88 kg.
		5	ACETONITRILE	3.90 kg.
		6	ISOPROPYL ALCOHOL	1.97 kg.
		7	METHYLENE CHLORIDE (MDC)	6.15 kg.
		8	N-[(S)-1-CARBETHOXYBUTY](S)ALANINE	0.85 kg.

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

Case No.	143 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	HETERO LABS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023													
HQ File Number	HQRNORM APPLY 00002168AM23													
RA File Number	09AX04000297 AM23													
Licence No and Date	0911003374/21/07/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>(3R)-TETRAHYDRO-3-FURANYL-4-METHYLBENZENE SULFONATE</td> <td>1 kg</td> <td>1</td> <td>Tetra Hydro Furan</td> <td>4.00 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	(3R)-TETRAHYDRO-3-FURANYL-4-METHYLBENZENE SULFONATE	1 kg	1	Tetra Hydro Furan	4.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
(3R)-TETRAHYDRO-3-FURANYL-4-METHYLBENZENE SULFONATE	1 kg	1	Tetra Hydro Furan	4.00 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	144 / NC/3/MEET/Aug/202324/11																			
Case Status	Case Approved																			
Party Name	VASUDHA PHARMA CHEM LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023																			
HQ File Number	HQRNORM APPLY 00002239AM23																			
RA File Number	26AX04000026 AM23																			
Licence No and Date	2611000646/25/07/2022																			
Norms Committee Decision:																				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																				
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="3">2-BUTYL-4-FORMYL IMIDAZOLE (OR) 2-BUTYL-1H-IMIDAZOLE-5-CARBOXALDEHYDE</td> <td rowspan="3">1 kg.</td> <td>1</td> <td>2 N BUTYL 4 CHLORO 5 FORMYL IMIDAZOLE</td> <td>1.41 kg.</td> </tr> <tr> <td>2</td> <td>METHANOL</td> <td>0.96 kg.</td> </tr> <tr> <td>3</td> <td>METHYLENE DI CHLORIDE OR</td> <td>0.83 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	2-BUTYL-4-FORMYL IMIDAZOLE (OR) 2-BUTYL-1H-IMIDAZOLE-5-CARBOXALDEHYDE	1 kg.	1	2 N BUTYL 4 CHLORO 5 FORMYL IMIDAZOLE	1.41 kg.	2	METHANOL	0.96 kg.	3	METHYLENE DI CHLORIDE OR	0.83 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.																
2-BUTYL-4-FORMYL IMIDAZOLE (OR) 2-BUTYL-1H-IMIDAZOLE-5-CARBOXALDEHYDE	1 kg.	1	2 N BUTYL 4 CHLORO 5 FORMYL IMIDAZOLE	1.41 kg.																
		2	METHANOL	0.96 kg.																
		3	METHYLENE DI CHLORIDE OR	0.83 kg.																

			METHYLENE CHLORIDE	
		4	ACTIVATED CARBON SC 40 V	0.05 kg.

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

Case No.	145 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	VASUDHA PHARMA CHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00002240AM23
RA File Number	26AX04000027 AM23
Licence No and Date	2611000647/25/07/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
LOSARTAN POTASSIUM (OR) LOSARTAN POTASSIUM USP (White to off white Powder)	1 kg.	1	2 CYANO 4 BROMOMETHYL BIPHENYL	0.75 kg.
		2	TOLUENE	0.444 kg.
		3	2 N BUTYL 4 CHLORO 5 FORMYL IMIDAZOLE	0.50 kg.
		4	METHANOL	0.815 kg.
		5	SODIUM BORO HYDRIDE	0.048 kg.
		6	SODIUM AZIDE	0.38 kg.
		7	ACTIVATED CARBON SC 40 V	0.100 kg.
		8	ISO PROPYL ALCOHOL	0.91 kg.

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

Case No.	146 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00002246AM23
RA File Number	09AX04000299 AM23
Licence No and Date	0911003396/25/07/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
3-(3-ISOPROPYL-5-METHYL-4H-1,2,4-TRIAZOL-4-YL)EXO-8-AZA-BICYCLO[3.2.1] OCTANE	1 kg.	1	Nortropinone.HCl	1.88 kg.
		2	Tetra Hydro Furan	3.32 kg.
		3	ACETONITRILE	3.77 kg.

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

Case No.	147 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	S.V.CHEM INTERMEDIATES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00002400AM23
RA File Number	04AX04000404 AM23
Licence No and Date	0411003747/02/08/2022

Norms Committee Decision:

The case under consideration for want of comments of TE.

Case No.	148 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred

Party Name	NIFTY LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00002449AM23
RA File Number	09AX04000391 AM23
Licence No and Date	0911003436/03/08/2022
Norms Committee Decision:	
The case under consideration for want of comments of TE.	

Case No.	149 / NC/3/MEET/Aug/202324/11
Case Status	Case Rejected
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00000793AM24
RA File Number	07AX04000657 AM23
Licence No and Date	0711004850/05/08/2022
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	150 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	PRACHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00002520AM23
RA File Number	08AX04000754 AM23
Licence No and Date	0811005702/08/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	151 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00002560AM23

RA File Number	34AX04000414 AM23
Licence No and Date	3411002630/10/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	152 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	BEST VALUE CHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM APPLY 00002625AM23			
RA File Number	34AX04000448 AM23			
Licence No and Date	3411002646/12/08/2022			
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:-				

Case No.	153 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00002668AM23
RA File Number	05AX04001382 AM23
Licence No and Date	0511014320/17/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	154 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			

Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00002697AM23
RA File Number	08AX04000846 AM23
Licence No and Date	0811005777/22/08/2022
Norms Committee Decision: The committee considered the case as per agenda and it was decided to fix ad-hoc norms as per SION A-412. RA concerned may take further necessary action as per above decision of NC.	

Case No.	155 / NC/3/MEET/Aug/202324/11													
Case Status	Case Approved													
Party Name	MICRO LABS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023													
HQ File Number	HQRNORM APPLY 00002737AM23													
RA File Number	07AX04000747 AM23													
Licence No and Date	0711005078/23/08/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC-3/MEET/Feb/202223/20 dated 24/02/2023 against advance authorization No. 0711005409 dated 06/10/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>PREMIX OF NIFUROXAZIDE((Each gm of Premix Contains Nifuroxazide BP 0.552 gm) {Nifuroxazide Net Content is 3477.60kg })</td><td>6300 kg.</td><td>1</td><td>NIFUROXAZIDE BP / EP</td><td>3512.376 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	PREMIX OF NIFUROXAZIDE((Each gm of Premix Contains Nifuroxazide BP 0.552 gm) {Nifuroxazide Net Content is 3477.60kg })	6300 kg.	1	NIFUROXAZIDE BP / EP	3512.376 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
PREMIX OF NIFUROXAZIDE((Each gm of Premix Contains Nifuroxazide BP 0.552 gm) {Nifuroxazide Net Content is 3477.60kg })	6300 kg.	1	NIFUROXAZIDE BP / EP	3512.376 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	156 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	TIDE INDUSTRIES			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			

HQ File Number	HQRNORM APPLY 00002755AM23													
RA File Number	34AX04000497 AM23													
Licence No and Date	3411002675/24/08/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Oct/202223/11 dated 31/10/2022 against advance authorization No. 3411000697 dated 04/06/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td rowspan="2">Gamma Undecalactone(Aldehyde C14)</td><td rowspan="2">1 kg.</td><td>1</td><td>Acrylic Acid</td><td>0.843 kg.</td></tr><tr><td>2</td><td>Di tert Butyl Peroxide</td><td>0.25 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	Gamma Undecalactone(Aldehyde C14)	1 kg.	1	Acrylic Acid	0.843 kg.	2	Di tert Butyl Peroxide	0.25 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
Gamma Undecalactone(Aldehyde C14)	1 kg.	1	Acrylic Acid	0.843 kg.										
		2	Di tert Butyl Peroxide	0.25 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	157 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	HONOUR LAB LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM REVIW00004631AM24			
RA File Number	09AX04000430 AM23			
Licence No and Date	0911003559/30/08/2022			
Norms Committee Decision:				
The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to ratify ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

			5-triyl triacetate/(1S)-1,5-Anhydro-1-C-[4-chloro-3-[[4-[[[(3S)-tetrahydro3furanyl]oxy]phenyl]methyl]phenyl]Dglucitol tetraacetate	
RA concerned may take further necessary action as per above decision of				

Case No.	158 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	HI-PURITY CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00002877AM23
RA File Number	03AX04002948 AM23
Licence No and Date	0311017592/01/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	159 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00003036AM23
RA File Number	05AX04001577 AM23
Licence No and Date	0511014727/09/09/2022
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:-4. 1. Yield given in last step is very low. Please give technical justification supported by technical literature. 2. By-product from last step alongwith sale-value 3. Since the firm is also exporting Cefitibutene, complete details upto API stage may be furnished. 4. Requirements of 7-Amin-3 Nor-3-cephem-4-carboxylic acid per kg. of Cefitibutene may be furnished.	

Case No.	160 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023

HQ File Number	HQRNORM APPLY 00003064AM23
RA File Number	05AX04001671 AM23
Licence No and Date	0511014757/12/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	161 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00003158AM23
RA File Number	05AX04001697 AM23
Licence No and Date	0511014860/16/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	162 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	TULIP LAB PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM APPLY 00003167AM23			
RA File Number	03AX04003046 AM23			
Licence No and Date	0311017934/16/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

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

Case No.	163 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00003190AM23
RA File Number	30AX04000248 AM23
Licence No and Date	3011002599/19/09/2022
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.	164 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00003244AM23
RA File Number	34AX04000595 AM23
Licence No and Date	3411002799/20/09/2022
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.	165 / NC/3/MEET/Aug/202324/11
Case Status	Case Rejected
Party Name	LASENOR INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00003295AM23
RA File Number	50AX04000050 AM23
Licence No and Date	5011000587/22/09/2022
Norms Committee Decision: The committee considered the application of the firm and it has been observed that the firm has not appeared for personal hearing before committee to explain their case, therefore, the committee decided to reject the application of the firm.	

Case No.	166 / NC/3/MEET/Aug/202324/11
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Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00003330AM23
RA File Number	05AX04001819 AM23
Licence No and Date	0511014976/23/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. **NC/3/MEET/Apr/202324/1 dated 28/04/2023** against advance authorization **No.0511016690 dated 03/01/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Tobramycin Inhalation Solution, USP, 300mg/ 4ml (Having net content of 25.20 kg of Bulk drug)	1 Number Pack	1	TOBRAMYCIN USP	306 mg.

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

Case No.	167 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004632AM24
RA File Number	09AX04000541 AM23
Licence No and Date	0911003683/23/09/2022

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to ratify ad-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.
EMPAGLIFLOZIN	1 kg.	1	(3R,4S,5S,6R)-3,4,5-Trihydroxy-6-(Hydroxymethyl) tetrahydro-2H-pyran-2-one	Not Required
		2	(S)-3-(4-(5-Bromo-2-Chloro benzyl) phenoxy) tetrahydrofuran	Not Required

		3	(2R,3R,4R,5S,6S)-2-(Acetoxymethyl)-6-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl)tetrahydro-2H-pyran- 3,4,5-triyl triacetate/(1S)-1,5-Anhydro-1-C-[4-chloro-3-[[4-[[[(3S)-tetrahydro3furanyl]oxy]phenyl]methyl]phenyl]Dglucitol tetraacetate	1.525 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	168 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00003358AM23
RA File Number	03AX04002988 AM23
Licence No and Date	0311018145/25/09/2022
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. Yields given in the reply are confusing and not conforming to applied norms. ii. Material Balance for each step not given. iii. Requirement and Recovery of solvents not shown in the details given.	

Case No.	169 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	VINS BIOPRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00003701AM23
RA File Number	09AX04000630 AM23
Licence No and Date	0911003795/13/10/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Details of steps involved in the manufacturing of Tetanus Antitoxin I.H.S/B.P 1500 IU including wastage at each steps of manufacturing	

2. **Justification of claiming 12% wastage.**
3. **Batch manufacturing record and material reconciliation sheet duly signed by dealing executive/manager.**
4. **DML (Drug manufacturing License)**

Case No.	170 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00003801AM23
RA File Number	09AX04000575 AM23
Licence No and Date	0911003827/18/10/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
HOMOSALATE	1 kg.	1	METHYL SALICYLATE	0.649 kg.

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

Case No.	171 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	HAFFKINE BIO PHARMACEUTICAL CORPORATION LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00003863AM23
RA File Number	03AX04003507 AM23
Licence No and Date	0311018754/20/10/2022

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/May/202324/2** dated **12/05/2023** against advance authorization **No.0311009905** dated **30/12/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Oral Polio Vaccine (OPV) with VVM	5000000.0 Numbers	1	Monovalent Bulk for Poliomyelitis Type I	665.5 Liters
		2	Monovalent Bulk for Poliomyelitis Type III	423.5 Liters
		3	Vaccine Vial (VVM)	5120000 Numbers

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

Case No.	172 / NC/3/MEET/Aug/202324/11
Case Status	Case Rejected
Party Name	LASENOR INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00004068AM23
RA File Number	50AX04000062 AM23
Licence No and Date	5011000669/04/11/2022
Norms Committee Decision:	
The committee considered the application of the firm and it has been observed that the firm has not appeared for personal hearing before committee to explain their case, therefore, the committee decided to reject the application of the firm.	

Case No.	173 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00004336AM23
RA File Number	05AX04002273 AM23
Licence No and Date	0511015796/14/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	174 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00004468AM23
RA File Number	34AX04000711 AM23
Licence No and Date	3411003022/18/11/2022
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.	175 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00004503AM23
RA File Number	09AX04000712 AM23
Licence No and Date	0911003988/21/11/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
TYPHOID CONJUGATE VACCINE MONOVALENT 5 DOSE 2.5ML VIAL WITH VACCINE VIAL MONITOR (VVM)	10,00,000 vials	1	GLASS VIALS	10,20,000 Numbers
		2	RUBBER STOPPERS	10,20,000 Numbers
		3	HEATMARKER VACCINE VIAL MONITOR LABELS (VVM LABELS)	1010,000 Numbers
		4	SHIPPING INDICATORS (Q TAGS)	660 Numbers
		5	FILTERS & FILTER AIDS	21 Numbers

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

Case No.	176 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00004512AM23
RA File Number	09AX04000684 AM23
Licence No and Date	0911003996/21/11/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Details of steps involved in the manufacturing wastage at each steps of manufacturing. 2. Justification of claiming 20% wastage. 3. Batch manufacturing record and material reconciliation sheet duly signed by dealing executive/manager. 4. DML (Drug manufacturing License)	

Case No.	177 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	INDO AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00001065AM24
RA File Number	03AX04004219 AM23
Licence No and Date	0311019745/05/12/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	178 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00002179AM24
RA File Number	05AX04002676 AM23
Licence No and Date	0511016292/12/12/2022
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-	

Export Product	Qty.	Sl. No.	Import Items	Qty.
Mydrimax Eye Drops 5 ml (Each ml containing 8 mg Tropicamide)	1 Number Vial	1	Tropicamide	40.8 mg / 5 ml vial

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

Case No.	179 / NC/3/MEET/Aug/202324/11
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004236AM24
RA File Number	03AX04004519 AM23
Licence No and Date	0311020036/16/12/2022

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.

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

Case No.	180 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	AURA PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005276AM23
RA File Number	03AX04004700 AM23
Licence No and Date	0311020263/26/12/2022

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.
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ARGYROL 0.5% / SILVER VITELLINATE NASAL DROPS 0.5 % w/v (EACH 10 ML CONTAINS 52 MG OF SILVER VITELLINATE)	1 Number	1	SILVER VITELLINATE	51.00 mg.
ARGYROL 1 % / SILVER VITELLINATE NASAL DROPS 1 % w/v (EACH 10 ML CONTAINS 104 MG OF SILVER VITELLINATE)	1 Number	2	SILVER VITELLINATE	102.00 mg
RA concerned may take further necessary action as per above decision of NC				

Case No.	181 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005387AM23
RA File Number	05AX04002796 AM23
Licence No and Date	0511016607/28/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	182 / NC/3/MEET/Aug/202324/11										
Case Status	Case Approved										
Party Name	CENTRIENT PHARMACEUTICALS INDIA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023										
HQ File Number	HQRNORM APPLY 00005408AM23										
RA File Number	30AX04000407 AM23										
Licence No and Date	3011002957/29/12/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>Atorvastatin Calcium</td><td>1 kg.</td><td>1</td><td>Thorase Enzyme</td><td>0.134 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	Atorvastatin Calcium	1 kg.	1	Thorase Enzyme	0.134 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.							
Atorvastatin Calcium	1 kg.	1	Thorase Enzyme	0.134 kg.							

		2	Chloroacetaldehyde SOL 45% CAA	0.81 kg.
		3	Heptane	0.63 kg.
		4	Iso Propyl Alcohol	3.40 kg.
		5	2,2 Dimethoxy Propane	0.60 kg.

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

Case No.	183 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	CENTRIENT PHARMACEUTICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005440AM23
RA File Number	30AX04000435 AM23
Licence No and Date	3011002966/30/12/2022

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.
Rosuvastatin Calcium	10000 kg.	1	Thorase Enzyme	2230.0 kg
		2	Chloroacetaldehyde SOL 45% CAA	13460.0 kg
		3	Heptane S	10490.0 kg
		4	2,2 Dimethoxy Propane	8700.0 kg
		5	BTSH (2-Mercapto-I-H-Bezothiazole	8940.0 kg
		6	Iso Propyl Alcohol	70560.0 kg

		7	Z8(RSV Side Chain) 4-(4-Fluorolphenyl)-6-Isopropyl - 2(Nmethyl Sulfonyl amino)pyrimidinyl-5-yl-fomyl	13130.0 kg
		8	2-Methyl Tetrahydrofuran	70520.0 kg
		9	Furfurylamine	2850.0 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	184 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005442AM23
RA File Number	05AX04002802 AM23
Licence No and Date	0511016635/30/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	185 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	SIDDHARTH CARBOCHEM PRODUCTS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM REVIW00003327AM24			
RA File Number	03AX04004857 AM23			
Licence No and Date	0311020368/30/12/2022			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-				
Export Product	Qty.	Sl. No.	Import Items	Qty.
METHYL SALICYLATE (MIN 99 PERCENT) (PHENOL FREE)	1 kg.	1	SALICYLIC ACID	1.1715 kg.

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

Case No.	186 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	ZENITH DYEINTERMEDIATES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005458AM23
RA File Number	03AX04004689 AM23
Licence No and Date	0311020392/02/01/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
NAS5((2-Diazo -1-Naphthol-5-Sulfonic Acid, Sodium Salt))	999000 kg.	1	Tobias Acid	161638.0 kg.

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

Case No.	187 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005594AM23
RA File Number	07AX04001479 AM23
Licence No and Date	0711006109/06/01/2023

Norms Committee Decision:

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

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

Furosemide Injection 10mg/mL - 10mL Vial (Furosemide Injection 10mg/mL-10mL Vial - filled with 100mg of furosemide as bulk drug mixed in water for injection and filled in 10mL Vial and capped with 20mm Bromobutyl Grey Rubber Stopper)	1 Numbers	1	S-127 4432/50/GREY Westar? RS SIL 1(20mm Grey Chlorobutyl Rubber Stopper - RFS)	Relevant as per Packing Policy
Rocuronium Bromide Injection 5mg/ml - 5mL Vial (Rocuronium Bromide Injection 5mg/ml-5mL Vial - Filled with 50mg of Rocuronium Bromide USP 10 mg as bulk drug filled in 5mL vial and capped with 20mm Bromobutyl Grey Rubber Stopper)	1 Numbers	2	S-127 4432/50/GREY Westar? RS SIL 1(20mm Grey Chlorobutyl Rubber Stopper - RFS)	Relevant as per Packing Policy

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

Case No.	188 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005595AM23
RA File Number	07AX04001473 AM23
Licence No and Date	0711006137/06/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	189 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	MACLEODS PHARMACEUTICALS LTD			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM REVIW00002168AM24			
RA File Number	03AX04005022 AM23			
Licence No and Date	0311020561/09/01/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 3690.000 kgs Dolutegravir Sodium + 22140.000 kgs Tenofovir Disoproxil Fumarate + 22140.000 kgs Lamivudine))	1 Number	1	(R)-3-AMINO-1-BUTANOL	19.635 mg.
		2	1-(2,2-dimethoxyethyl)-5-methoxy-6(methoxycarbonyl) 4-oxo-1,4-dihydropyridine-3-carboxylic acid	70.125 mg
		3	(R)-9-(2-phosphonomethoxy propyl)-adenine	205.02 mg
		4	LAMIVUDINE	306.00 mg

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

Case No.	190 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005741AM23
RA File Number	07AX04001550 AM23
Licence No and Date	0711006194/16/01/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
LISINOPRIL 2.5MG TABLETS(LISINOPRIL 2.5MG TABLETS 7.50 KG)	1 Number	1	LISINOPRIL DIHYDRATE BP/EP/IP/USP	2.55 mg/tablet
LISINOPRIL 5MG TABLETS(LISINOPRIL 5MG TABLETS 30 KG)	1 Number	2	LISINOPRIL DIHYDRATE BP/EP/IP/USP	5.10 mg/tablet
LISINOPRIL 10 MG TABLETS(LISINOPRIL 10 MG TABLETS 130 KG)	1 Number	3	LISINOPRIL DIHYDRATE BP/EP/IP/USP	10.2 mg/tablet
LISINOPRIL 20MG TABLETS(LISINOPRIL 20MG TABLETS 240 KG)	1 Number	4	LISINOPRIL DIHYDRATE BP/EP/IP/USP	20.4 mg/tablet

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

Case No.	191 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004701AM24
RA File Number	07AX04001546 AM23
Licence No and Date	0711006197/16/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	192 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00005768AM23
RA File Number	05AX04003041 AM23
Licence No and Date	0511016882/17/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	193 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	CLARIANT INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004661AM24
RA File Number	03AX04005405 AM23
Licence No and Date	0311021129/03/02/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	194 / NC/3/MEET/Aug/202324/11
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Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00006286AM23
RA File Number	03AX04005525 AM23
Licence No and Date	0311021390/13/02/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Dec/202223/17 dated 13/01/2023** against advance authorization **No.0311017097 dated 11/08/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Bempedoic Acid and Ezetimibe Fixed Dose Combination Tablets (Each Tablet content Bempedoic Acid 180mg and Ezetimibe 10mg(Net content of Bempedoic Acid 3492 kg and Ezetimibe 194 kg in total Export Qty) (AA for Free of cost material as per Para 4.11 of HBP & Para 4.19 of FTP & RBI Master Circular C-26 Disallowing remittances for material being supplied free of cost.)	1 Number	1	Bempedoic Acid	189.90 mg.
		2	Ezetimibe	10.55 mg.

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

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

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

Case No.	195 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00006352AM23
RA File Number	03AX04005586 AM23
Licence No and Date	0311021482/16/02/2023

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per

details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
BELGUARD PBSA (Phenylbenzimidazole Sulfonic Acid)	1 kg.	1	Ortho Phenylene Diamine	0.4925 kg.

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

Case No.	196 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00006401AM23
RA File Number	09AX04001029 AM23
Licence No and Date	0911004487/17/02/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
SALISOL HS (PBSA) / Ensulizole (2-Phenylbenzimidazole-5-sulfonic acid)	1 kg.	1	ORTHO PHENYLENEDIAMINE	0.55 kg.
		2	BENZALDEHYDE	0.545 kg.

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

Case No.	197 / NC/3/MEET/Aug/202324/11
Case Status	Case Approved
Party Name	MACLEODS PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM REVIW00004527AM24

RA File Number	03AX04005710 AM23																						
Licence No and Date	0311021583/24/02/2023																						
Norms Committee Decision:																							
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																							
<table border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty.</th></tr> </thead> <tbody> <tr> <td rowspan="4">Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 5400.000 kgs Dolutegravir Sodium + 32400.000 kgs Tenofovir Disoproxil Fumarate + 32400.000 kgs Lamivudine))</td><td rowspan="4">1 Number</td><td>1</td><td>(R)-3-AMINO-1-BUTANOL</td><td>19.635 mg.</td></tr> <tr> <td>2</td><td>1-(2,2-dimethoxyethyl)-5-methoxy-6(methoxycarbonyl) 4-oxo-1,4-dihydropyridine-3-carboxylic acid</td><td>70.125 mg</td></tr> <tr> <td>3</td><td>(R)-9-(2-phosphonomethoxy propyl)-adenine</td><td>205.02 mg</td></tr> <tr> <td>4</td><td>LAMIVUDINE</td><td>306.00 mg</td></tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 5400.000 kgs Dolutegravir Sodium + 32400.000 kgs Tenofovir Disoproxil Fumarate + 32400.000 kgs Lamivudine))	1 Number	1	(R)-3-AMINO-1-BUTANOL	19.635 mg.	2	1-(2,2-dimethoxyethyl)-5-methoxy-6(methoxycarbonyl) 4-oxo-1,4-dihydropyridine-3-carboxylic acid	70.125 mg	3	(R)-9-(2-phosphonomethoxy propyl)-adenine	205.02 mg	4	LAMIVUDINE	306.00 mg
Export Product	Qty.	Sl. No.	Import Items	Qty.																			
Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 5400.000 kgs Dolutegravir Sodium + 32400.000 kgs Tenofovir Disoproxil Fumarate + 32400.000 kgs Lamivudine))	1 Number	1	(R)-3-AMINO-1-BUTANOL	19.635 mg.																			
		2	1-(2,2-dimethoxyethyl)-5-methoxy-6(methoxycarbonyl) 4-oxo-1,4-dihydropyridine-3-carboxylic acid	70.125 mg																			
		3	(R)-9-(2-phosphonomethoxy propyl)-adenine	205.02 mg																			
		4	LAMIVUDINE	306.00 mg																			
RA concerned may take further necessary action as per above decision of NC.																							

Case No.	198 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	SIDDHARTH CARBOCHEM PRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00006742AM23
RA File Number	03AX04005555 AM23
Licence No and Date	0311021882/03/03/2023
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. Copy of Shipping Bill and Bill of Entry. 2. Production/Consumption data for last year duly certified by GST. 3. Quantity and value of By-Product obtained with copy of invoice.	

Case No.	199 / NC/3/MEET/Aug/202324/11
Case Status	Case Deferred
Party Name	ANUH PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023
HQ File Number	HQRNORM APPLY 00006763AM23
RA File Number	03AX04005850 AM23
Licence No and Date	0311021914/06/03/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	200 / NC/3/MEET/Aug/202324/11			
Case Status	Case Approved			
Party Name	AUROBINDO PHARMA LTD			
Meeting Number and Date	NC/ 3/ MEET/ Aug/ 202324/ 11 and 22/08/2023			
HQ File Number	HQRNORM APPLY 00006808AM23			
RA File Number	09AX04001078 AM23			
Licence No and Date	0911004655/08/03/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				