



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

रोड, नई दिल्ली

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Jul/202425/7

DATED: 06/08/2024

Please Note

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

Meeting No. NC/3/MEET/Jul/202425/7 dated 06/08/2024 of Norms Committee - III for the year 2024-25 was held on 06/08/2024 under the Chairmanship of Shri Rakesh Kumar, Additional DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2023.

The following members were present in the meeting:-

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

2	Shri Raman Kumar,Deputy DGFT	DGFT(HQ)
3	Shri Uttam Dey Sarkar, Assistant Section Officer	DGFT (HQ)
4	Shri SHAISH KUMAR,Technical Consultant	DGFT
5	Shri DINESHNARAIN MATHUR,Technical Consultant	DGFT
6	Shri Nand Lal,Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	TROIKAA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00001967AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Export quantity in number of Injections. 2. Export description as per Drug ManufacturingLicence (DML). 3. Copy of DML. 4. Master-Batch Formula with net content of inputs in export item.	

Case No.	2 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00007891AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the Deptt. of Bio-Technology, it was decided to call for the following information/documents from the firm:- 1. Technical process flow diagram of manufacturing of export product involving all the imported items and wastages involved at each step. 2. Batch manufacturing record and material reconciliation sheet duly signed by the dealing executive/manager. 3. Drug Manufacturing Licence	

Case No.	3 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00009177AM24
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 item in meeting **No.1/82-ALC4/2018 dated 01/05/2018** against advance authorization **No.0910064564dated 09/01/2017**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-Phenyl Acetamideo-3-Chloromethyl Cephalosporanic Acid Para-Methoxy Benzyl Ester)	1 kg	1	Penicillin G Potassium First Crystal	1.61 kg.
		2	Acetone	1.971 kg.
		3	Isopropyl Alcohol	0.66 kg.
		4	Methylene Chloride (MDC)	3.29 kg.
		5	2 Mercapto Benzo Thiazole (MBT)	0.511 kg.
		6	Methanol	1.971 kg.

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

Case No.	4 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00009180AM24
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 item in meeting **No.1/82-ALC4/2018 dated 01/05/2018** against advance authorization **No.0910064564dated 09/01/2017**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-Phenyl Acetamideo-3-Chloromethyl Cephalosporanic Acid Para-Methoxy Benzyl Ester)	1 kg	1	Penicillin G Potassium First Crystal	1.61 kg.
		2	Acetone	1.971 kg.
		3	Isopropyl Alcohol	0.66 kg.
		4	Methylene Chloride (MDC)	3.29 kg.
		5	2 Mercapto Benzo Thiazole (MBT)	0.511 kg.
		6	Methanol	1.971 kg.

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

Case No.	5 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00009184AM24
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 item in meeting **No.1/82-ALC4/2018 dated 01/05/2018** against advance authorization **No.0910064564dated 09/01/2017**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-Phenyl Acetamideo-3-Chloromethyl Cephalosporanic Acid Para-Methoxy Benzyl Ester)	1 kg	1	Penicillin G Potassium First Crystal	1.61 kg.
		2	Acetone	1.971 kg.
		3	Isopropyl Alcohol	0.66 kg.
		4	Methylene Chloride (MDC)	3.29 kg.
		5	2 Mercapto Benzo Thiazole (MBT)	0.511 kg.
		6	Methanol	1.971 kg.

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

Case No.	6 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00009186AM24
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 item in meeting **No.1/82-ALC4/2018 dated 01/05/2018** against advance authorization **No.0910064564dated 09/01/2017**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-Phenyl Acetamideo-3-Chloromethyl Cephalosporanic Acid Para-Methoxy Benzyl Ester)	1 kg	1	Penicillin G Potassium First Crystal	1.61 kg.
		2	Acetone	1.971 kg.
		3	Isopropyl Alcohol	0.66 kg.
		4	Methylene Chloride (MDC)	3.29 kg.
		5	2 Mercapto Benzo Thiazole (MBT)	0.511 kg.
		6	Methanol	1.971 kg.

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

Case No.	7 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00009191AM24
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 item in meeting **No.1/82-ALC4/2018 dated 01/05/2018** against advance authorization **No.0910064564dated 09/01/2017**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-Phenyl Acetamideo-3-Chloromethyl Cephalosporanic Acid Para-Methoxy Benzyl Ester)	1 kg	1	Penicillin G Potassium First Crystal	1.61 kg.
		2	Acetone	1.971 kg.
		3	Isopropyl Alcohol	0.66 kg.
		4	Methylene Chloride (MDC)	3.29 kg.
		5	2 Mercapto Benzo Thiazole (MBT)	0.511 kg.
		6	Methanol	1.971 kg.

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

Case No.	8 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	SMS LIFESCIENCES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00009304AM24
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 item in meeting **No.13/82-ALC4/2019 dated 31/01/2020** against advance authorization **No.0910067021dated 01/01/2019**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
(3R,3aS,6ar)-Hexa Hydro Furo-[2,3-b]- Furan-3-YL-4-Nitro Phenyl Carbonate (DAV-IIA)(Intermediate of Darunavir)	1 kg.	1	BIS IV(Hexa Hydro Furo [2,3- B] Furan-3-OL)	1.61 kg.
		2	Methylene Di Chloride	5.32 kg.

Note: No repeat licence will be allowed on above norms.

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

Case No.	9 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00001977AM25

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 item in meeting No. 33/82-ALC4/2012 dated 21/03/2013 against advance authorization No.0810118232 dated 06/02/2013, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">CALCITRIOL CAPSULES BP 0.25 MCG</td> <td rowspan="2">45496000 Number</td> <td>1</td> <td>CALCITRIOL BP</td> <td>11,601.463 mg.</td> </tr> <tr> <td>2</td> <td>TRIGLYCERIDES, MEDIUM CHAIN PH EUR</td> <td>7049.868 kg.</td> </tr> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CALCITRIOL CAPSULES BP 0.25 MCG	45496000 Number	1	CALCITRIOL BP	11,601.463 mg.	2	TRIGLYCERIDES, MEDIUM CHAIN PH EUR	7049.868 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
CALCITRIOL CAPSULES BP 0.25 MCG	45496000 Number	1	CALCITRIOL BP	11,601.463 mg.										
		2	TRIGLYCERIDES, MEDIUM CHAIN PH EUR	7049.868 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	10 / NC/3/MEET/Jul/202425/7								
Case Status	Case Approved								
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024								
HQ File Number	HQRNORM APPLY 00001756AM25								
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 item in meeting No.NC/3/MEET/May/202425/4 dated 06/06/2024 against advance authorization No. 0511024521 dated 15/03/2024 it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					

Nepafenac Ophthalmic Suspension, 0.1% w/v NEPALACT Sterile Eye Drops, 5ml) (PRANAYAM)((Each ml contains Nepafenac 1.0 mg (Equivalent to 100.000 Gram of Bulk Drug))	20000 Numbers	1	Nepafenac	102 gm
RA concerned may take further necessary action as per above decision of NC.				

Case No.	11 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00001755AM25
RA File Number	NA
Licence No and Date	NA

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Latanoprost and Timolol Maleate Ophthalmic Solution 0.005% w/v/0.5% w/v, 2.5ml Each ml contains Latanoprost 0.05 mg (Net 7.500 Gm) and Timolol Maleate 6.83 mg = Timolol 5 mg (Net 1024.5 Gm))	1 Number	1	TIMOLOL MALEATE	17.94 mg.
		2	LATANOPROST	0.1275 mg.

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

Case No.	12 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	FINE ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00001277AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- (i) Step wise manufacturing process. (ii) Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. (iii) Complete technical details as per Annexure to Appendix 4E for chemical products. (iv) Stoichiometric balance between import and export on molar basis. (v) Details of indigenous input with quantity. (vi) FFA content in import item Refined Rapeseed Oil. (vii) Why refined oil is used to manufacture oleochemical?	

Case No.	13 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00000017AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sofosbuvir	1 kg.	1	(2R)-N-Benzoyl-2-Deoxy-2-Fluoro-2-Methyl cytidine 3,5-Dibenzoate (or) Cytidine,N-Benzoyl-2-Deoxy-2-Fluoro-2-Methyl-3,5-Dibenzoate-(2R)	1.567 kg.
		2	N-[(S)-(2,3,4,5,6-Pentafluoro phenoxy) phenoxy phosphinyl]-L-Alanine 1-Methyl Ethyl Ester (or) Propan-2-yl(2S)-2-{[(Penta fluorophenoxy) Phenoxy) Phosphoryl] Amino}Propanoate	1.467 kg.
		3	Tetrahydrofuran	6.75 kg.

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

Case No.	14 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00000291AM25
RA File Number	NA
Licence No and Date	NA

Norms Committee Decision:

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

1. As per flow chart item of export is shown as Pine oil while in the application item of export is Terpineol, please clarify.
2. Certificate of Analysis (CoA) of export Terpineol.
3. Quantity and value of by-products obtained with copy of invoices.
4. Justification of 50% wastage in manufacture process (stage wise).

Case No.	15 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00000293AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Manufacture details furnished is for export of Pine Oil while export is Dihydromyrcenol. Please furnish relevant details.	

Case No.	16 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00000325AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Eplerenone	1 kg.	1	(7A,17A)-17-Hydroxy-3-oxo-pregna-4,9(11)-diene-7,21-dicarboxylic acid g-lactone methyl ester	1.42 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	17 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00000412AM25
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 item in meeting **No. NC/3/MEET/Jun/202223/5** dated **08/07/2022** against advance authorization **No.3111000428** dated **29/06/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
N-METHYL-2-PYRROLIDONE (ORGANIC CHEMICAL)	1 kg.	1	METHANOL	0.370 kg.
		2	AMMONIA ANHYDROUS	0.160 kg.
		3	14 BUTANEDIOL	1.044 kg.

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

Case No.	18 / NC/3/MEET/Jul/202425/7										
Case Status	Case Approved										
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024										
HQ File Number	HQRNORM APPLY 00000350AM25										
RA File Number	NA										
Licence No and Date	NA										
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="197 918 1428 1152"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> <tr> <td>FAVIPIRAVIR</td><td>1 kg.</td><td>1</td><td>6-Fluoro-3-Hydroxypyrazine-2-Carbonitrile Dicyclohexylaminesalt</td><td>1.282 kg.</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	FAVIPIRAVIR	1 kg.	1	6-Fluoro-3-Hydroxypyrazine-2-Carbonitrile Dicyclohexylaminesalt	1.282 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
FAVIPIRAVIR	1 kg.	1	6-Fluoro-3-Hydroxypyrazine-2-Carbonitrile Dicyclohexylaminesalt	1.282 kg.							

Case No.	19 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00000344AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
FAVIPIRAVIR	1 kg.	1	6-Fluoro-3-Hydroxypyrazine-2-Carbonitrile Dicyclohexylaminesalt	1.282 kg.

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

Case No.	20 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00000345AM25
RA File Number	NA
Licence No and Date	NA

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
FAVIPIRAVIR	1 kg.	1	6-Fluoro-3-Hydroxypyrazine-2-Carbonitrile Dicyclohexylaminesalt	1.282 kg.

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

Case No.	21 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	OPTRIX LABORATORIES PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024

and Date	
HQ File Number	HQRNORM APPLY 00000346AM25
RA File Number	NA
Licence No and Date	NA

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
LINEZOLID	1 kg.	1	3,4-Difluoro Nitrobenzene OR 3,4 Di FluoroNitrobenzene	0.80 kg.
		2	(s)-Epichlorohydrin (OR) (s)-(+)-2-(chloromethyl)oxirane	0.80 kg.

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

Case No.	22 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	NECTAR LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001482AM25
RA File Number	222404000083 AM14
Licence No and Date	2210015019/15/07/2014

Norms Committee Decision:

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

Certificate of Analysis (CoA) of export item showing content of API and coating material.

Case No.	23 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	MEGHMANI INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001542AM25
RA File Number	082404000293 AM17
Licence No and Date	0810139050/22/11/2016

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No. 07/AM21** dated **24.12.2020** against advance authorization **No.0810139050** dated **22.11.2016**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BROMOKETAL	1 kg.	1	2,4 DichloroAceteophenone	0.546 kg.
		2	1,2 Pentandiol	0.326 kg.
		3	Cychlohexane	0.100 kg.

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

Case No.	24 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001636AM25
RA File Number	092404000606 AM17

Licence No and Date	0910065115/31/05/2017																													
Norms Committee Decision:																														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.1/82-ALC4/2018 dated 01/05/2018 against advance authorization No.0910064564dated 09/01/2017 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="6">GCLE(7-Phenyl Acetamideo-3-Chloromethyl Cephalosporanic Acid Para-Methoxy Benzyl Ester)</td><td rowspan="6">1 kg</td><td>1</td><td>Penicillin G Potassium First Crystal</td><td>1.61 kg.</td></tr><tr><td>2</td><td>Acetone</td><td>1.971 kg.</td></tr><tr><td>3</td><td>Isopropyl Alcohol</td><td>0.66 kg.</td></tr><tr><td>4</td><td>Methylene Chloride (MDC)</td><td>3.29 kg.</td></tr><tr><td>5</td><td>2 Mercapto Benzo Thiazole (MBT)</td><td>0.511 kg.</td></tr><tr><td>6</td><td>Methanol</td><td>1.971 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	GCLE(7-Phenyl Acetamideo-3-Chloromethyl Cephalosporanic Acid Para-Methoxy Benzyl Ester)	1 kg	1	Penicillin G Potassium First Crystal	1.61 kg.	2	Acetone	1.971 kg.	3	Isopropyl Alcohol	0.66 kg.	4	Methylene Chloride (MDC)	3.29 kg.	5	2 Mercapto Benzo Thiazole (MBT)	0.511 kg.	6	Methanol	1.971 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																										
GCLE(7-Phenyl Acetamideo-3-Chloromethyl Cephalosporanic Acid Para-Methoxy Benzyl Ester)	1 kg	1	Penicillin G Potassium First Crystal	1.61 kg.																										
		2	Acetone	1.971 kg.																										
		3	Isopropyl Alcohol	0.66 kg.																										
		4	Methylene Chloride (MDC)	3.29 kg.																										
		5	2 Mercapto Benzo Thiazole (MBT)	0.511 kg.																										
		6	Methanol	1.971 kg.																										
RA concerned may take further necessary action as per above decision of NC.																														

Case No.	25 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001635AM25
RA File Number	092404000316 AM17
Licence No and	0910065116/31/05/2017

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.1/82-ALC4/2018 dated 01/05/2018 against advance authorization No.0910064564dated 09/01/2017, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-Phenyl Acetamideo-3-Chloromethyl Cephalosporanic Acid Para-Methoxy Benzyl Ester)	1 kg	1	Penicillin G Potassium First Crystal	1.61 kg.
		2	Acetone	1.971 kg.
		3	Isopropyl Alcohol	0.66 kg.
		4	Methylene Chloride (MDC)	3.29 kg.
		5	2 Mercapto Benzo Thiazole (MBT)	0.511 kg.
		6	Methanol	1.971 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	26 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001634AM25
RA File Number	092404000480 AM18
Licence No and Date	0910066143/12/04/2018
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.1/82-ALC4/2018 dated 01/05/2018** against advance authorization **No.0910064564 dated 09/01/2017**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-PHENYL ACETAMIDEO-3CHLORO METHYL CEPHALOSPORANIC ACID PARA METHOXY BENZYL ESTER)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.61 kg.
		2	ACETONE	1.971 kg.
		3	ISOPROPYL ALCOHOL	0.66 kg.
		4	METHYLENE CHLORIDE (MDC)	3.29 kg.
		5	2 MERCAPTO BENZO THIAZOLE(MBT)	0.511 kg.
		6	METHANOL	1.971 kg.

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

Case No.	27 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	SMILAX LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001518AM25
RA File Number	092404000128 AM19

Licence No and Date	0910066351/19/06/2018													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>PANTOPRAZOLE BASE</td><td>1 kg.</td><td>1</td><td>MALTOL</td><td>0.80 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PANTOPRAZOLE BASE	1 kg.	1	MALTOL	0.80 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
PANTOPRAZOLE BASE	1 kg.	1	MALTOL	0.80 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	28 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	PALADIN PAINTS & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001511AM25
RA File Number	039504000456 AM19
Licence No and Date	0310823254/24/08/2018
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical reaction indicating molecular weight of both reactant & products indicating Stoichiometric material balance on molar basis. 2. The percentage of yield of the reaction	

Case No.	29 / NC/3/MEET/Jul/202425/7
Case Status	Case Rejected
Party Name	TATA CHEMICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	018205001646AM19
RA File Number	039504000901 AM19
Licence No and Date	0310825645/13/12/2018
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that Norms Committee-3 in its Meeting No. NC/3/MEET/Aug/202122/7 dated 13/08/2021 has already decided to transfer the case to Norms Committee-6 as the export product – Fossence (Oligofructose/FOS) Powder P 90/Liquid L95 comes under Food category. Therefore, Committee decided to close the case.	

Case No.	30 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00002022AM25
RA File Number	052304000507 AM19
Licence No and Date	0510409676/15/02/2019
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Drug Manufacturing Licence (DML) showing approved composition. 2. Copy of Advance Authorisation to show actual export and import quantity, if amended in the licence.	

Case No.	31 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	REFLUX PHARMACEUTICALS
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001943AM25
RA File Number	039504000931 AM20
Licence No and	0310833815/01/01/2020

Date	
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Copy of technical literature in support of molar excess and percentage yield.	

Case No.	32 / NC/3/MEET/Jul/202425/7																
Case Status	Case Approved																
Party Name	AQUILA ORGANICS PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024																
HQ File Number	HQRNORM REVIW00001956AM25																
RA File Number	039404000879 AM20																
Licence No and Date	0310834406/22/01/2020																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202324/25 dated 11/03/2024 against advance authorization No.0310830783 dated 02/08/2019 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">7-Acetyl-1,1,3,4,4,6-Hexamethyl 1,2,3,4-Tetrahydro Naphthalene</td><td rowspan="2">1 kg.</td><td>1</td><td>2,3 Dimethyl 1 Butene</td><td>1.19 kg.</td></tr><tr><td>2</td><td>PARACYMENE</td><td>1.03 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	7-Acetyl-1,1,3,4,4,6-Hexamethyl 1,2,3,4-Tetrahydro Naphthalene	1 kg.	1	2,3 Dimethyl 1 Butene	1.19 kg.	2	PARACYMENE	1.03 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
7-Acetyl-1,1,3,4,4,6-Hexamethyl 1,2,3,4-Tetrahydro Naphthalene	1 kg.	1	2,3 Dimethyl 1 Butene	1.19 kg.													
		2	PARACYMENE	1.03 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	33 / NC/3/MEET/Jul/202425/7
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Case Status	Case Approved
Party Name	ARENE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00006628AM24
RA File Number	092404000024 AM21
Licence No and Date	0910068681/28/04/2020

Norms Committee Decision:

The representative of the firm attended personal hearing thorough Video Concerence and explained their case. The Committee heard the explanation of the firm and after due deliberation, it was decided to fix the norms based on Production/Consumption Data provided by the firm as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Oseltamivir Phosphate	1468 kg.	1	Ethyl(3R,4S,5S)4,5-Epoxy-3-(1-ethylpropoxy)cyclohex-1-ene-1-carboxylate/	5000 kg.
		2	Sodium Azide	913 kg.
		3	Acetonitrile	3244 kg.
		4	Dimethyl Formamide	5872 kg.
		5	Isopropyl alcohol	4404 kg.

Note: The above norms are for regularization and closure purposes only.

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

Case No.	34 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved

Party Name	BROOKS LABORATORIES LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024																		
HQ File Number	HQRNORM REVIW00001377AM25																		
RA File Number	302404000010 AM21																		
Licence No and Date	3010105213/02/06/2020																		
Norms Committee Decision:																			
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. 14/82-ALC4/2018 dated 14/02/2019 against advance authorization No.2210015917 dated 12/06/2018 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																			
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Meropenem Injection USP1000 mg.Each vial contains Sterile Meropenem Trihydrate USP equ to AnhydrousMeropenem1000mg(SterileSodiumCarbonateUSPequtoSodium90.2mg</td><td>1 Number</td><td>1</td><td>MEROPENEM WITH SODIUM CARBONATE USP</td><td>0.690 gm/500 mg vial</td></tr><tr><td>Meropenem Injection 500 mg USPEach vial contains Sterile Meropenem Trihydrate USP equ to AnhydrousMeropenem500mg(SterileSodiumCarbonateUSPequtoSodium90.2mg</td><td>1 Number</td><td>2</td><td>MEROPENEM WITH SODIUM CARBONATE USP</td><td>1.380 gm/1 gm vial</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Meropenem Injection USP1000 mg.Each vial contains Sterile Meropenem Trihydrate USP equ to AnhydrousMeropenem1000mg(SterileSodiumCarbonateUSPequtoSodium90.2mg	1 Number	1	MEROPENEM WITH SODIUM CARBONATE USP	0.690 gm/500 mg vial	Meropenem Injection 500 mg USPEach vial contains Sterile Meropenem Trihydrate USP equ to AnhydrousMeropenem500mg(SterileSodiumCarbonateUSPequtoSodium90.2mg	1 Number	2	MEROPENEM WITH SODIUM CARBONATE USP	1.380 gm/1 gm vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Meropenem Injection USP1000 mg.Each vial contains Sterile Meropenem Trihydrate USP equ to AnhydrousMeropenem1000mg(SterileSodiumCarbonateUSPequtoSodium90.2mg	1 Number	1	MEROPENEM WITH SODIUM CARBONATE USP	0.690 gm/500 mg vial															
Meropenem Injection 500 mg USPEach vial contains Sterile Meropenem Trihydrate USP equ to AnhydrousMeropenem500mg(SterileSodiumCarbonateUSPequtoSodium90.2mg	1 Number	2	MEROPENEM WITH SODIUM CARBONATE USP	1.380 gm/1 gm vial															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	35 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	KusuMa PharMa
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001447AM25
RA File Number	039404000115 AM21
Licence No and Date	0310836572/08/06/2020
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Sep/202223/8dated 23/09/2022** against advance authorization **No.0311008529dated 13/11/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SACCHARIN POWDER (PURE/AR) (DENTAL GRADE) (Not less than 98% purity)	1 kg.	1	SODIUM SACCHARIN	1.38 kg.

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

Case No.	36 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	REFLUX PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001944AM25
RA File Number	NA
Licence No and Date	0311001445/03/02/2021
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Copy of technical literature in support of molar excess and percentage yield.	

Case No.	37 / NC/3/MEET/Jul/202425/7
Case Status	Case Rejected

Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001998AM25
RA File Number	09AA04004523 AM21
Licence No and Date	0911000350/15/02/2021
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	38 / NC/3/MEET/Jul/202425/7																
Case Status	Case Approved																
Party Name	BHAGWATI INDUSTRIES																
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024																
HQ File Number	HQRNORM APPLY 00219420AM22																
RA File Number	08AA04033013 AM22																
Licence No and Date	0811002934/21/10/2021																
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><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Chloral Anhydrous</td><td rowspan="2">1 kg.</td><td>1</td><td>Ethyl Alcohol</td><td>0.878 kg.</td></tr><tr><td>2</td><td>Caustic Soda</td><td>0.20 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Chloral Anhydrous	1 kg.	1	Ethyl Alcohol	0.878 kg.	2	Caustic Soda	0.20 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Chloral Anhydrous	1 kg.	1	Ethyl Alcohol	0.878 kg.													
		2	Caustic Soda	0.20 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	39 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001995AM25
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 taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Jun/202122/2 dated 02/07/2021** against advance authorization **No.0910051360dated 21/02/2012**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
RACTOPAMINE HCL (for Veterneryuse)	1 kg.	1	RS 4 2 AMINO 1 HYDROXY ETHYL PHENOL HCL	0.446 kg.
		2	4 HYDROXY BENZALDEHYDE	0.70 kg.

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

Case No.	40 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00299344AM22
RA File Number	07AA04038998 AM22
Licence No and Date	0711002737/28/12/2021

Norms Committee Decision:

The representative of the firm attended personal hearing thorough Video Concerence and explain their case. The Committee heard the explanation of the firmand after due deliberation it was directed to firm

to furnish the following information/documents for further consideration:-

1. **Complete balanced chemical reaction, indicating molecular weight or reactant(s) and product/s with overall yield of the reaction with justification.**
2. **Production of the export item viz-à-viz consumption of raw materials for the specific export which is in question. (Not all the products of the company) for the last three years duly certified by Chartered Accountant.**
3. **End use of export item(s) with copy of norms, if the same is fixed in the past.**

Case No.	41 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00380949AM22
RA File Number	34AX04000157 AM22
Licence No and Date	3411001935/09/03/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
AZITHROMYCIN MONOHYDRATE	1 kg.	1	Erythromycin Thiocyanate (on 100% activity basis)	1.865 kg.A
		2	Hydroxylamine Hydrochloride	0.540 kg.
		3	Acetone	3.44 kg.
		4	IPA	1.58 kg.
		5	Platinum Oxide	1.00 gm.

		6	Triethylamine	0.30 kg.
		7	Methylene Chloride	3.16 kg.
		8	Activated Carbon	0.020 kg.

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

Case No.	42 / NC/3/MEET/Jul/202425/7
Case Status	Case Rejected
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00386056AM22
RA File Number	08AX04000650 AM22
Licence No and Date	0811004377/14/03/2022
Norms Committee Decision:	
The firmhas informed that they have surrendered their above license to RA. Therefore, the Committee decided to close the application of the firm.	

Case No.	43 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	ARENE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00000197AM23
RA File Number	09AX04000016 AM23
Licence No and Date	0911002850/12/04/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
AMLODIPINE BASE	1 kg.	1	Phthalic anhydride	0.870 kg.
		2	Monoethanolamine	0.356 kg.
		3	Toluene	2.40 kg.
		4	Ethyl 4-chloroacetoacetate	0.993 kg.
		5	Acetic Acid	4.40 kg.
		6	Ortho ChloroBenzaldehyde	0.775 kg.
		7	Methyl Aceto Acetate	1.40 kg.
		8	Methanol	1.25 kg.

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

Case No.	44 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00008588AM24
RA File Number	52AX04000039 AM23
Licence No and Date	5211002485/13/05/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
5-NITROSO-2,4,6- TRIAMINOPYRIMIDINE(5- NITROSO-2,4,6- TRIAMINOPYRIMIDINE)	1 kg.	1	MALONONITRILE	0.571 kg.
		2	GUANIDINE HCL	0.826 kg.
		3	N,N DIMETHYL FORMAMIDE 99.5% (Tech. Spec. Liquid)	3.465 kg.

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

Case No.	45 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00000912AM23
RA File Number	09AX04000058 AM23
Licence No and Date	0911003033/20/05/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Jan/202324/21 dated 24/01/2024** against advance authorization **No.0911006014 dated 17/10/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Colistimethate sodium powder for preparation of solution for inhalation 1000000 Units(Each vial contains: Colistimethate sodium 1000000 U (corresponds to approximately 80 mg))	340000 Numbers	1	ColistimethateSodium	26.687 kg.

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

Case No.	46 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	METROPOLITAN EXIMCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00000920AM23
RA File Number	03AX04000550 AM23
Licence No and Date	0311014915/22/05/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TETRABROMOBISPHENOL A BIS (DIBROMOMETHYL PROPYL ETHER)	1 kg.	1	SAYTEX CP 2000 TETRABROMOBISPHENOL A TBBPA	0.683 kg.
		2	METHALLYL CHLORIDE	0.227 kg.

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

Case No.	47 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00000980AM23
RA File Number	03AX04000822 AM23

Licence No and Date	0311014992/25/05/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical reaction indicating molecular weight of both reactant and the products with yield of the reaction. 2. Stoichiometric material balance on a molar basis. 3. Concentration of the ammonia in aqueous solution and accordingly, calculation of requirement of both the chemicals.	

Case No.	48 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	ZENFOLD SUSTAINABLE TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00001090AM23
RA File Number	09AX04000132 AM23
Licence No and Date	0911003083/31/05/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. How many moles of each reactant is used to manufactured export product. 2. Provide Stoichiometric balance on molar basis to arrive at the quantity of raw material. 3. Percentage yield on molar basis at each stage of reaction.	

Case No.	49 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00005924AM23
RA File Number	03AX04001050 AM23

Licence No and Date	0311015297/07/06/2022				
Norms Committee Decision:					
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-					
Sl. No.	Export Product	Qty.	Import Items		Qty. allowed.
1	Clobetasol Propionate Foam 0.05percent 50gm((Net. wt. of Net. wt. of Clobetasol Propionate USP (Micronized) is5.00 Kgs)	200000 Numbers	CLOBETASOL (MICRONIZED)	PROPIONATE USP	36.295 kg.
2	Clobetasol Propionate Foam 0.05percent 100gm((Net. wt. of Clobetasol Propionate USP (Micronized) is 10.00 Kgs.))	200000 Numbers			
3	Clobetasol Propionate Cream USP 0.05percent (Pack Size 15gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.15 Kgs))	200000 Numbers			
4	Clobetasol Propionate Cream USP 0.05percent (Pack size 30gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.300 Kgs))	200000 Numbers			
5	Clobetasol Propionate Cream USP 0.05percent (Pack size 45 gm)((Net Weight of Clobetasol Propionate USP (Micronized) 1.125 Kgs))	50000 Numbers			
6	Clobetasol Propionate Cream USP 0.05percent (Pack size 60gm)((Net Weight of Clobetasol Propionate USP (Micronized) 1.500 Kgs))	50000 Numbers			
7	Clobetasol Propionate Ointment USP 0.05percent (Pack size 15gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.375 Kgs))	50000 Numbers			

8	Clobetasol Propionate Ointment USP 0.05percent (Pack size 30gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.750 Kgs))	50000 Numbers
9	Clobetasol Propionate Ointment USP 0.05percent (Pack size 45gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.900 Kgs))	40000 Numbers
10	Clobetasol Propionate Ointment USP 0.05percent (Pack size 60gm)((Net Weight of Clobetasol Propionate USP (Micronized) 0.600 Kgs))	20000 Numbers
11	Clobetasol Propionate Spray 0.05percent (Pack size 59ml)((Net Weight of Clobetasol Propionate USP (Micronized) 1.180 Kgs))	40000 Numbers
12	Clobetasol Propionate Spray 0.05percent (Pack size 125ml)((Net Weight of Clobetasol Propionate USP (Micronized) 2.500 Kgs))	40000 Numbers
13	Clobetasol Prop. Top Sol USP, 0.05percent 25ml((Net Weight of Clobetasol Propionate USP (Micronized) 0.625 Kgs))	50000 Numbers
14	Clobetasol Prop. Top Sol USP, 0.05percent 50ml((Net Weight of Clobetasol Propionate USP (Micronized) 1.50 Kgs))	60000 Numbers
15	Clobetasol Pro Shampoo, 0.05 percent 118ml((Net Weight of Clobetasol Propionate USP (Micronized) 3.54 Kgs))	60000 Numbers
16	Clobetasol Propionate Foam 0.05percent 100gm (Emulsion Formulation)((Net. wt. of Clobetasol Propionate USP (Micronized) is 2.50 Kgs.))	50000 Numbers

17 Clobetasol Propionate Foam 0.05percent 50000
 50gm (Emulsion Formulation)((Net. wt. of Numbers
 Clobetasol Propionate USP

 (Micronized) is 1.250 Kgs.))

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

Case No.	50 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00001347AM23
RA File Number	05AX04000669 AM23
Licence No and Date	0511013173/13/06/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. To give balance chemical reaction indicating molecular weight of all the reactants and product with stage wise yield of the reaction. 2. To indicate where Alumino Silicate Catalyst, Denatured Ethyl alcohol and methanol are used in the chemical reaction giving their application/use. 3. Calculation of the requirement of all the chemicals with justification of low yield.	

Case No.	51 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00006007AM23
RA File Number	03AX04001989 AM23
Licence No and Date	0311016055/04/07/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Momate AZ NASAL SPRAY 150 MD /Mometasone Furoate & Azelastine HCL Nasal Spray (150MD)((Net Wt. of Azelastine Hydrochloride BP 5250 Grams))	250000 Numbers	1	Azelastine Hydrochloride BP	5355 grams
Mometasone Furoate & Azelastine Hydrochloride Nasal Spray (75MD)(Momat Rino Advance 75 MD/MOMATE AZ NASAL SPRAY 75 MD/(GLENSPRAY ACTIVE 75 NS Pack size : 75 MD bottle (Net Wt. of Azelastine Hydrochloride BP 2100 Grams))	200000 Numbers	2	Azelastine Hydrochloride BP	2142 grams

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

Case No.	52 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00007068AM24
RA File Number	05AX04001017 AM23
Licence No and Date	0511013648/07/07/2022
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PBA - (4-CHLORO 2-FLUORO 3-METHOXY PHENYL) BORONIC ACID	1 kg.	1	2-Fluorophenol	0.83 kg.
		2	Toluene (Bulk)	0.12 kg.
		3	Lithium Metal	0.100 kg.
		4	Monoglyme (1, 2 Dimethoxyethane)	0.80 kg.
		5	Mixed Hexanes	0.29 kg.
		6	Trimethyl borate	0.79 kg.

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

Case No.	53 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	SHREE GANESH REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00001895AM23
RA File Number	34AX04000273 AM23
Licence No and Date	3411002508/07/07/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export	

product/import item in meeting **No.NC/3/MEET/Jun/202122/2 dated 02/07/2021** against advance authorization **No.3411000551dated 11/05/2021** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DI METHYL AMINO PROPYL CHLORIDE HYDROCHLORIDE 65% SOLUTION IN WATER (DMPC- 65%)	1 kg.	1	1-BROMO-3-CHLORO PROPANE	0.72 kg.

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

Case No.	54 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00001959AM23
RA File Number	03AX04002151 AM23
Licence No and Date	0311016241/11/07/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
RIVAROXABAN EP	1 kg.	1	4 4 AMINOPHENYL MORPHOLINE 3 ONE	0.713 kg.
		2	S N 2 3 EPOXYPROPYL PHTHALIMIDE	Item not shown in the process/reaction. Hence not allowed.

		3	5 CHLOROTHIOPHENE 2 CARBOXYLIC ACID OR 2 OXIRAN 2 YL METHYL ISOINDOLINE 1 3 DIONE	Both are not the same items. Hence not allowed
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RA concerned may take further necessary action as per above decision of NC.

Case No.	55 / NC/3/MEET/Jul/202425/7										
Case Status	Case Approved										
Party Name	FRESENIUS KABI ONCOLOGY LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024										
HQ File Number	HQRNORM APPLY 00001963AM23										
RA File Number	05AX04001045 AM23										
Licence No and Date	0511013693/11/07/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jun/202425/5 dated 14/06/2024 against advance authorization No.0511004178 dated 18/08/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Ropivacaine Hydrochloride Anhydrous(API)</td><td>1 kg.</td><td>1</td><td>S)-2',6' Pipecoloxylidide OR (S)-N-(2,6-dimethy phenyl-2-piperidinecarboxamide)</td><td>0.923 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ropivacaine Hydrochloride Anhydrous(API)	1 kg.	1	S)-2',6' Pipecoloxylidide OR (S)-N-(2,6-dimethy phenyl-2-piperidinecarboxamide)	0.923 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Ropivacaine Hydrochloride Anhydrous(API)	1 kg.	1	S)-2',6' Pipecoloxylidide OR (S)-N-(2,6-dimethy phenyl-2-piperidinecarboxamide)	0.923 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	56 / NC/3/MEET/Jul/202425/7
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Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00001993AM23
RA File Number	34AX04000353 AM23
Licence No and Date	3411002522/12/07/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Copy of Master-Batch Formula showing the net content of inputs in export item.	

Case No.	57 / NC/3/MEET/Jul/202425/7										
Case Status	Case Approved										
Party Name	KusuMa PharMa										
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024										
HQ File Number	HQRNORM REVIW00000597AM24										
RA File Number	03AX04002093 AM23										
Licence No and Date	0311016291/12/07/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202425/2dated 30/04/2024 against advance authorization No.0311024234 dated 05/06/2023 , 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>E.D.T.A. DI SODIUM(PURE/AR)</td><td>1 kg.</td><td>1</td><td>EDTA ACID</td><td>0.80 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	E.D.T.A. DI SODIUM(PURE/AR)	1 kg.	1	EDTA ACID	0.80 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
E.D.T.A. DI SODIUM(PURE/AR)	1 kg.	1	EDTA ACID	0.80 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	58 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00007416AM24
RA File Number	34AX04000357 AM23
Licence No and Date	3411002528/13/07/2022

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. allowed.
ORTHO NITRO TOLUENE	1 kg.	1	NITRIC ACID 68%	0.675 kg. .
		2	TOLUENE	0.661 kg.
		3	SULPHURIC ACID 98%	Deleted, procured from indigenous source
		4	SODA ASH	Deleted, procured from indigenous source

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

Case No.	59 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024

HQ File Number	HQRNORM APPLY 00002011AM23
RA File Number	52AX04001578 AM23
Licence No and Date	5211002817/13/07/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Details of items Methylene chloride and Methanol in the process and justify the high requirement of these two. 2. Yield of the reaction and giving calculation for the requirement of all the chemicals. 3. Current Production/Consumption data duly endorsed by CA.	

Case No.	60 / NC/3/MEET/Jul/202425/7																							
Case Status	Case Approved																							
Party Name	AURORE LIFE SCIENCES PRIVATE LIMITED																							
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024																							
HQ File Number	HQRNORM APPLY 00002017AM23																							
RA File Number	09AX04000301 AM23																							
Licence No and Date	0911003338/13/07/2022																							
Norms Committee Decision:																								
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jun/202425/6dated 01/07/2024 against advance authorization No.0911004646 dated 08/03/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																								
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="4">4-(2-(2-(6,6-dimethylbicyclo [3.1.1] heptan-2-yl)ethoxy)ethyl) morpholine(intermediate)</td><td rowspan="4">1 kg.</td><td>1</td><td>DIHYDRONOPOL</td><td>0.66 kg.</td></tr><tr><td>2</td><td>TOLUENE</td><td>1.915 kg.</td></tr><tr><td>3</td><td>SODAMIDE</td><td>0.19 kg.</td></tr><tr><td>4</td><td>METHANOL</td><td>0.56 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	4-(2-(2-(6,6-dimethylbicyclo [3.1.1] heptan-2-yl)ethoxy)ethyl) morpholine(intermediate)	1 kg.	1	DIHYDRONOPOL	0.66 kg.	2	TOLUENE	1.915 kg.	3	SODAMIDE	0.19 kg.	4	METHANOL	0.56 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																				
4-(2-(2-(6,6-dimethylbicyclo [3.1.1] heptan-2-yl)ethoxy)ethyl) morpholine(intermediate)	1 kg.	1	DIHYDRONOPOL	0.66 kg.																				
		2	TOLUENE	1.915 kg.																				
		3	SODAMIDE	0.19 kg.																				
		4	METHANOL	0.56 kg.																				

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

Case No.	61 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002018AM23
RA File Number	09AX04000333 AM23
Licence No and Date	0911003339/13/07/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Jun/202425/6dated 01/07/2024** against advance authorization **No.0911004646 dated 08/03/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-(2-(2-(6,6-dimethylbicyclo [3.1.1] heptan-2-yl)ethoxy)ethyl) morpholine(intermediate)	1 kg.	1	DIHYDRONOPOL	0.66 kg.
		2	TOLUENE	1.915 kg.
		3	SODAMIDE	0.19 kg.
		4	METHANOL	0.56 kg.

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

Case No.	62 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002019AM23
RA File Number	09AX04000338 AM23
Licence No and Date	0911003340/13/07/2022
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	63 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002067AM23
RA File Number	34AX04000361 AM23
Licence No and Date	3411002535/15/07/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Jun/202425/5** dated **14/06/2024** against advance authorization **No.3410046549** dated **13/11/2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ointment(Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1 % - 15 gm	1 Number	1	Nystatin USP	238.65 mg.
Ointment(Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1 % - 30 gm	1 Number	2	Nystatin USP	477.30 mg.
Ointment(Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% - 60 gm	1 Number	3	Nystatin USP	954.61 mg.
Cream(Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% - 15 gm	1 Number	4	Nystatin USP	238.65 mg

Cream(Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% - 30 gm	1 Number	5	Nystatin USP	477.30 mg.
Cream(Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% - 60 gm	1 Number	6	Nystatin USP	954.61 mg

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

Case No.	64 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002087AM23
RA File Number	09AX04000341 AM23
Licence No and Date	0911003356/15/07/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Amoxicillin and Clavulanate Potassium Tablets 375 mg [300+75 mg](Each tablet contains 300 mg Amoxicillin astrihydrate and 75 mg Clavulanic Acid as Clavulanate Potassium.)	1 Number	1	6-Amino Penicillanic Acid	199.464 mg.
		2	D-(-)-4-hydroxyphenylglycine methyl ester	172.25 mg.
		3	Diluted Clavulanate Potassium (1:1)	182.264 mg.
Amoxicillin and Clavulanate Potassium Tablets 250 mg [200+50 mg](Each tablet contains 200 mg Amoxicillin astrihydrate and 50 mg	1 Number	4	6-Amino Penicillanic Acid	132.976 mg.
		5	D-(-)-4-hydroxyphenylglycine methyl ester	114.834 mg.

Clavulanic Acid as Clavulanate Potassium.)		6	Diluted Clavulanate Potassium (1:1)	121.509 mg.
Amoxicillin and Clavulanate Potassium Tablets 125 mg [100+25 mg](Each tablet contains 100 mg Amoxicillin astrihydrate and 25 mg Clavulanic Acid as Clavulanate Potassium.)	1 Number	7	6-Amino Penicillanic Acid	66.488 mg.
		8	D-(-)-4-hydroxyphenylglycine methyl ester	57.417 mg.
		9	Diluted Clavulanate Potassium (1:1)	60.755 mg.
Amoxicillin and Clavulanate Potassium Tablets 62.5 mg [50+12.50](Each tablet contains 50 mg Amoxicillin astrihydrate and 12.5 mg Clavulanic Acid as Clavulanate Potassium.)	1 Number	10	6-Amino Penicillanic Acid	33.244 mg.
		11	D-(-)-4-hydroxyphenylglycine methyl ester	28.708 mg.
		12	Diluted Clavulanate Potassium (1:1)	30.377 mg.

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

Case No.	65 / NC/3/MEET/Jul/202425/7			
Case Status	Case Approved			
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024			
HQ File Number	HQRNORM APPLY 00002187AM23			
RA File Number	09AX04000313 AM23			
Licence No and Date	0911003379/21/07/2022			
Norms Committee Decision:				
The Committee considered the 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:-				

				allowed.
(1S,4R)-4-[(2-AMINO-6-CHLORO-5-1 kg. FORMAMIDO-4- PYRIMIDINYL)AMINO)-2- CYCLOPENTENE-1- METHANOL		1	VINCELACTAM	0.92 kg.
		2	N 2 AMINO 4 6 DICHLORO 5 PYRIMDINYL FORMAMIDE	0.764 kg.
		3	SODIUM BORO HYDRIDE	0.226 kg.
		4	L TARTARIC ACID	0.519 kg.
		5	D TARTARIC ACID	0.76 kg.

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

Case No.	66 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002221AM23
RA File Number	07AX04000559 AM23
Licence No and Date	0711004755/23/07/2022
Norms Committee Decision: The representative of the firm attended personal hearing thorough Video Concerence and explain their case. The Committee heard the explanation of the firmand after due deliberation it was directed to firm to furnish the following information/documents for further consideration:- I. Complete balanced chemical reaction, indicating molecular weight or reactant(s) and product/s with overall yield of the reaction with justification. II. Production of the export item viz-à-viz consumption of raw materials for the specific export which is in question. (not all the products of the company) for the last three years duly certified by Chartered Accountant. III. End use of export item(s) with copy of norms, if the same is fixed in the past.	

Case No.	67 / NC/3/MEET/Jul/202425/7														
Case Status	Case Approved														
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED														
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024														
HQ File Number	HQRNORM APPLY 00002279AM23														
RA File Number	31AX04000122 AM23														
Licence No and Date	3111001586/26/07/2022														
Norms Committee Decision:															
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-															
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 83.33% W/W WHITE GRANULESPOWDER</td><td>1 kg.</td><td>1</td><td>DICYANDIAMIDE (DCDA) WHITE POWDER</td><td>0.465 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 83.33% W/W WHITE GRANULESPOWDER	1 kg.	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.465 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.											
METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 83.33% W/W WHITE GRANULESPOWDER	1 kg.	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.465 kg.											
RA concerned may take further necessary action as per above decision of NC.															

Case No.	68 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002317AM23
RA File Number	09AX04000364 AM23
Licence No and Date	0911003412/28/07/2022
Norms Committee Decision:	
The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
LiHMDS 1.0M IN TETRAHYDROFURAN(CLEAR YELLOW TO BROWN COLOR LIQUID)	1 kg.	1	LITHIUM METAL 98PCT MIN	0.10 kg.
		2	HEXAMETHYLDISILAZANE	0.2367 kg.
		3	TETRAHYDROFURAN	0.712 kg.
		4	ISOPRENE	0.0508 kg.

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

Case No.	69 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002358AM23
RA File Number	34AX04000398 AM23
Licence No and Date	3411002586/29/07/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Copy of Master-Batch Formula showing net content of inputs in the export item.	

Case No.	70 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	METROPOLITAN EXIMCHEM PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024																
HQ File Number	HQRNORM APPLY 00002481AM23																
RA File Number	03AX04002332 AM23																
Licence No and Date	0311016872/04/08/2022																
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:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">TETRABROMOBISPHENOL A BIS (DIBROMOMETHYL PROPYL ETHER</td><td rowspan="2">1 kg.</td><td>1</td><td>SAYTEX CP 2000 TETRABROMOBISPHENOL A TBBPA</td><td>0.683 kg.</td></tr><tr><td>2</td><td>METHALLYL CHLORIDE</td><td>0.227 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	TETRABROMOBISPHENOL A BIS (DIBROMOMETHYL PROPYL ETHER	1 kg.	1	SAYTEX CP 2000 TETRABROMOBISPHENOL A TBBPA	0.683 kg.	2	METHALLYL CHLORIDE	0.227 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
TETRABROMOBISPHENOL A BIS (DIBROMOMETHYL PROPYL ETHER	1 kg.	1	SAYTEX CP 2000 TETRABROMOBISPHENOL A TBBPA	0.683 kg.													
		2	METHALLYL CHLORIDE	0.227 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	71 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002474AM23
RA File Number	34AX04000434 AM23
Licence No and Date	3411002610/04/08/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Copy of Master-Batch Formula showing net content of inputs, certified by Quality Control Incharge.	

Case No.	72 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00006414AM24
RA File Number	09AX04000207 AM23
Licence No and Date	0911003443/05/08/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant documents from the firm.	

Case No.	73 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002560AM23
RA File Number	34AX04000414 AM23
Licence No and Date	3411002630/10/08/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Provide Stoichiometric balance between import and export on molar basis. 2. Percentage yield of reaction. 3. Percentage purity of export product.	

Case No.	74 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	ALCHEMIE FINECHEM PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024																	
HQ File Number	HQRNORM APPLY 00002553AM23																	
RA File Number	03AX04002069 AM23																	
Licence No and Date	0311017059/10/08/2022																	
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:-																		
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">MONO METHYL META TOLUIDINE</td><td rowspan="2">1 kg.</td><td>1</td><td>META TOLUIDINE</td><td>0.834 kg.</td></tr><tr><td>2</td><td>DENATURED ETHYL ALCOHOL</td><td>0.360 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MONO METHYL META TOLUIDINE	1 kg.	1	META TOLUIDINE	0.834 kg.	2	DENATURED ETHYL ALCOHOL	0.360 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.														
MONO METHYL META TOLUIDINE	1 kg.	1	META TOLUIDINE	0.834 kg.														
		2	DENATURED ETHYL ALCOHOL	0.360 kg.														
RA concerned may take further necessary action as per above decision of NC.																		

Case No.	75 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002645AM23
RA File Number	03AX04002727 AM23
Licence No and Date	0311017254/16/08/2022
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	76 / NC/3/MEET/Jul/202425/7				
Case Status	Case Approved				

Party Name	AMNEAL INJECTABLES PRIVATE LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024																		
HQ File Number	HQRNORM APPLY 00002758AM23																		
RA File Number	08AX04000605 AM23																		
Licence No and Date	0811005824/24/08/2022																		
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:-																			
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Magnesium Sulfate In Water for Injection (0.325m Eq Mg++/mL) 40mg/mL2g Total (Each 50mLContains)-NET667.092KGS</td><td>1 Number</td><td>1</td><td>MEGNESIUM SULFATE HEPTAHYDRATE USP</td><td>2.00 gm.</td></tr><tr><td>Magnesium Sulfate In Water for Injection (0.325 mEq Mg++/mL) 40 mg/mL 4g Total (Each 100 mL Contains)-NET 257.908KGS</td><td>1 Number</td><td>2</td><td>MEGNESIUM SULFATE HEPTAHYDRATE USP</td><td>4.00 gm.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Magnesium Sulfate In Water for Injection (0.325m Eq Mg++/mL) 40mg/mL2g Total (Each 50mLContains)-NET667.092KGS	1 Number	1	MEGNESIUM SULFATE HEPTAHYDRATE USP	2.00 gm.	Magnesium Sulfate In Water for Injection (0.325 mEq Mg++/mL) 40 mg/mL 4g Total (Each 100 mL Contains)-NET 257.908KGS	1 Number	2	MEGNESIUM SULFATE HEPTAHYDRATE USP	4.00 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Magnesium Sulfate In Water for Injection (0.325m Eq Mg++/mL) 40mg/mL2g Total (Each 50mLContains)-NET667.092KGS	1 Number	1	MEGNESIUM SULFATE HEPTAHYDRATE USP	2.00 gm.															
Magnesium Sulfate In Water for Injection (0.325 mEq Mg++/mL) 40 mg/mL 4g Total (Each 100 mL Contains)-NET 257.908KGS	1 Number	2	MEGNESIUM SULFATE HEPTAHYDRATE USP	4.00 gm.															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	77 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002801AM23
RA File Number	09AX04000470 AM23
Licence No and Date	0911003541/26/08/2022
Norms Committee Decision:	

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

Case No.	78 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002813AM23
RA File Number	07AX04000768 AM23
Licence No and Date	0711005110/26/08/2022
Norms Committee Decision: The representative of the firm attended personal hearing thorough Video Concerence and explain their case. The Committee heard the explanation of the firmand after due deliberation it was directed to firm to furnish the following information/documents for further consideration:- I. Complete balanced chemical reaction, indicating molecular weight or reactant(s) and product/s with overall yield of the reaction with justification. II. Production of the export item viz-à-viz consumption of raw materials for the specific export which is in question. (Not all the products of the company) for the last three years duly certified by Chartered Accountant. III. End use of export item(s) with copy of norms, if the same is fixed in the past.	

Case No.	79 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	GODAVARI BIOREFINERIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002842AM23
RA File Number	03AX04002739 AM23
Licence No and Date	0311017558/29/08/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:-	

1. **Certificate of Analysis (CoA) of export item indicating moisture content in it.**
2. **Justification of quantity required for Denatured Ethyl Alcohol.**

Case No.	80 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002857AM23
RA File Number	09AX04000483 AM23
Licence No and Date	0911003562/30/08/2022

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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tofacitnab citrate	1 kg.	1	4-chloro-7H-pyrido[2,3-d]pyrimidine	1.00 kg.
		2	(3R,4R)-1-Benzyl-N,4-Dimethyl piperidin-3-amine dihydrochloride	1.72 kg.

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

Case No.	81 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002871AM23

RA File Number	08AX04000919 AM23			
Licence No and Date	0811005862/01/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Nystatin Cream, 100000 units/gm, 15gm(Each gram Contains: 100,000 USP Nystatin Units in an aqueous, cream base.	85000 Numbers	1	Nystatin USP(Nystatin Micronized USDMF GRADE)	20.466 kg.
Nystatin Cream, 100000 units/gm, 30gm(Each gram Contains: 100,000 USP Nystatin Units in anaqueous, cream base.	528750 Numbers	2	Nystatin USP(Nystatin Micronized USDMF GRADE)	259.708 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	82 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	HI-PURITY CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002877AM23
RA File Number	03AX04002948 AM23
Licence No and Date	0311017592/01/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dichlorophene	1 kg.	1	Para ChloroPhenol	1.006 kg.

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

Case No.	83 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002919AM23
RA File Number	34AX04000543 AM23
Licence No and Date	3411002729/02/09/2022
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	84 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00002944AM23
RA File Number	07AX04000812 AM23
Licence No and Date	0711005159/05/09/2022
Norms Committee Decision:	
The representative of the firm attended personal hearing through Video Conference and explain their case. The Committee heard the explanation of the firm and after due deliberation it was directed to firm	

to furnish the following information/documents for further consideration:-

- I. Complete balanced chemical reaction, indicating molecular weight or reactant(s) and product/s with overall yield of the reaction with justification.**
- II. Production of the export item viz-à-viz consumption of raw materials for the specific export which is in question. (Not all the products of the company) for the last three years duly certified by Chartered Accountant.**
- III. End use of export item(s) with copy of norms, if the same is fixed in the past.**

Case No.	85 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00003021AM23
RA File Number	34AX04000522 AM23
Licence No and Date	3411002756/09/09/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
FUMARIC ACID ENCAPSULATED 80%	1 MT	1	Fumaric Acid	0.80 MT
FUMARIC ACID ENCAPSULATED 85%	1 MT	2	Fumaric Acid	0.85 MT

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

Case No.	86 / NC/3/MEET/Jul/202425/7
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Case Status	Case Deferred
Party Name	INTIGREAT CONSULTING SERVICES LLP
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00003056AM23
RA File Number	03AX04002543 AM23
Licence No and Date	0311017790/12/09/2022
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	87 / NC/3/MEET/Jul/202425/7			
Case Status	Case Approved			
Party Name	SUDEEP NUTRITION PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024			
HQ File Number	HQRNORM APPLY 00003092AM23			
RA File Number	34AX04000422 AM23			
Licence No and Date	3411002775/13/09/2022			
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:-				

Case No.	88 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred

Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00003118AM23
RA File Number	09AX04000498 AM23
Licence No and Date	0911003623/14/09/2022
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	89 / NC/3/MEET/Jul/202425/7
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00003266AM23
RA File Number	08AX04001009 AM23
Licence No and Date	0811006072/21/09/2022
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:-	

Excipients. q.s.Colors: Titanium Dioxide and Yellow Oxide of Iron.				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	90 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00003251AM23
RA File Number	34AX04000590 AM23
Licence No and Date	3411002800/21/09/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Master Batch Formula	

Case No.	91 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00006256AM24
RA File Number	08AX04000971 AM23
Licence No and Date	0811006083/22/09/2022
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	92 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	KAVALIFE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00003326AM23
RA File Number	07AX04000884 AM23
Licence No and Date	0711005312/23/09/2022
Norms Committee Decision: The firm was called for Personal Hearing on 08/08/2024 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for Personal Hearing with relevant documents/information.	

Case No.	93 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00003339AM23
RA File Number	03AX04003267 AM23
Licence No and Date	0311018114/24/09/2022
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	94 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00003389AM23
RA File Number	08AX04001054 AM23
Licence No and	0811006114/26/09/2022

Date	
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	95 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00003395AM23
RA File Number	34AX04000620 AM23
Licence No and Date	3411002830/27/09/2022
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:-	
1. Copy of Master Batch Formula	

Case No.	96 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred
Party Name	VINYL PRODUCTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001983AM25
RA File Number	05AX04002721 AM23
Licence No and Date	0511016406/15/12/2022
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	97 / NC/3/MEET/Jul/202425/7
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Case Status	Case Rejected
Party Name	B G P HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM APPLY 00005000AM23
RA File Number	34AX04000827 AM23
Licence No and Date	3411003121/15/12/2022
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and it has been observed that Ion Exchange Resin is not a raw material for manufacturing of export item. Hence the committee has decided to reject the application of the firm.	

Case No.	98 / NC/3/MEET/Jul/202425/7			
Case Status	Case Approved			
Party Name	SAVA HEALTHCARE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024			
HQ File Number	HQRNORM APPLY 00006536AM23			
RA File Number	31AX04000353 AM23			
Licence No and Date	3111002045/23/02/2023			
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:-				

		6	Magnesium Oxide	294.26 kg.
		7	BETA TAB 20% S	28.40 kg.
		8	Folic acid	3.90 kg.
		9	Pyridoxine Hydrochloride	35.50 kg.
		10	Dry Vitamin E 50%	145.97 kg.
Pregnancy Multivitamin Folic 5 Tablet(Pack Size 2 x 30 Quantity Total No. of Tablets 2400000 Nos)	2400000 Numbers	11	Scoralite DC 90 MD	1040.55 kg.
		12	Niacinamide	24.48 kg.
		13	Ascorbic Acid, Granular	146.88 kg.
		14	Copper Gluconate	17.50 kg.
		15	Ferrous Fumarate	130.34 kg.
		16	Magnesium Oxide	101.47 kg.
		17	BETA TAB 20% S	9.80 kg.
		18	Folic acid	1.35 kg.
		19	Pyridoxine Hydrochloride	12.24 kg.
		20	Dry Vitamin E 50%	50.34 kg.

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

Case No.	99 / NC/3/MEET/Jul/202425/7
Case Status	Case Deferred

Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024
HQ File Number	HQRNORM REVIW00001706AM25
RA File Number	03AX04001312 AM24
Licence No and Date	0311025237/07/07/2023
Norms Committee Decision: The firm was called for Personal Hearing on 08/08/2024 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for Personal Hearing with relevant documents/information.	

Case No.	100 / NC/3/MEET/Jul/202425/7																						
Case Status	Case Approved																						
Party Name	SUPRIYA LIFESCIENCE LIMITED																						
Meeting Number and Date	NC/ 3/ MEET/ Jul/ 202425/ 7 and 06/08/2024																						
HQ File Number	HQRNORM REVIW00001325AM25																						
RA File Number	03AX04003085 AM24																						
Licence No and Date	0311028054/19/10/2023																						
Norms Committee Decision:																							
The Committee considered the request of the 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><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="4">RIBOFLAVIN SODIUM PHOSPHATE HYDRATE EP 11.2</td><td rowspan="4">1 kg.</td><td>1</td><td>RIBOFLAVIN (VITAMIN B2)</td><td>1.30 kg.</td></tr><tr><td>2</td><td>PYRIDINE</td><td>2.00 kg.</td></tr><tr><td>3</td><td>ACETONITRILE</td><td>1.73 kg.</td></tr><tr><td>4</td><td>PHOSPHORUS OXYCHLORIDE</td><td>2.00 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	RIBOFLAVIN SODIUM PHOSPHATE HYDRATE EP 11.2	1 kg.	1	RIBOFLAVIN (VITAMIN B2)	1.30 kg.	2	PYRIDINE	2.00 kg.	3	ACETONITRILE	1.73 kg.	4	PHOSPHORUS OXYCHLORIDE	2.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																			
RIBOFLAVIN SODIUM PHOSPHATE HYDRATE EP 11.2	1 kg.	1	RIBOFLAVIN (VITAMIN B2)	1.30 kg.																			
		2	PYRIDINE	2.00 kg.																			
		3	ACETONITRILE	1.73 kg.																			
		4	PHOSPHORUS OXYCHLORIDE	2.00 kg.																			

Note:

- I. Above ad-hoc norms are valid only for export to DSM Nutritional Product AG, Switzerland under Contract Manufacturing Agreement between DSM, Switzerland and M/s Supriya Lifescience Limited.**
- II. No fresh Advance Authorisation on above norms will be considered except for those already taken before 06/06/2024 and further Advance Authorisation to be considered based on revised yields and consumption data.**
- III. Above norms are for EP11.2 only and not for any other Pharmaceutical specification like EP/BP/USP etc.**
- IV. RA concerned may take further necessary action as per above decision of Norms Committee and conditions attached with the Norms.**