



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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

(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Mar/202324/25

DATED: 11/03/2024

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:
- II. The Norms Committee has taken decision only with respect to technical aspect/wastage norms. While redeeming the applications, RAs should check that the applicant has fulfilled all requirements as prescribed in policy/procedure including those in Policy Circulars issued from time to time or any other provisions under FTP/HBP for EODC.
- III. Wherever the Committee has fixed Norms, the concerned RA may ensure that AA is issued on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less.

Meeting No. NC/3/MEET/Mar/202324/25 dated 11/03/2024 of Norms Committee - III for the year 2023-24 was held on 11/03/2024 under the Chairmanship of to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2015-20.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	UTTAM SARKAR, Assistant Section Officer	DGFT(HQ)
2	Raman Kumar, Deputy DGFT	DGFT(HQ)
3	NAND Lal, Technical Consultant	DPIIT
4	SHAISH KUMAR, Technical Consultant	DGFT
5	DINESHNARAIN MATHUR, Technical Consultant	DGFT
6	Nand Lal, Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006691AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it has been observed that Advance Authorisation appears to be old. The export and import quantity given in the application are not matching. DML and MBF are not available to check. Therefore, it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with 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. Sample of shipping bills and bill of entry of the export products along with statement of Input-output as per export documents of the said authorization. vii. Copy of Master Batch Formula viii. Copy of Drug Manufacturing License	

Case No.	2 / NC/3/MEET/Mar/202324/25			
Case Status	Case Approved			
Party Name	SMILAX LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024			
HQ File Number	HQRNORM REVIW00008717AM24			
RA File Number	NA			
Licence No and Date	NA			
Norms Committee Decision:				
The Committee considered the request of the firm for fixation of ad-hoc norms against Advance Authorisation No. 0910061527 dated 13/01/2015 having RA File No. 092404000574AM15 and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol.1 as per details given below or as applied by the firm, whichever is less:-				

(R)-3- (Tert-butyl dimethyl silyloxy)-pentane-dioic acid mono tert-butyl ester (TB-17) (TERT-BUTYL 3R-TERT-BUTYL DIMETHYL SILYLOXY-GLUTARATE)	1 kg.	1	Dimethyl-3-Hydroxy Glutarate	1.106 kg.
		2	Ditertbutyl Dicarbonate	1.564 kg.
		3	Tertiary Butyl dimethyl Silyl Chloride	2.136 kg.
		4	Imidazole	1.319 kg.
		5	R-Phenylethyl amine	0.480 kg.
		6	Tertiary Butanol	1.310 kg.

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

Case No.	3 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	AQUILA ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008898AM24
RA File Number	NA
Licence No and Date	0310830783/null

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.
7-Acetyl-1,1,3,4,6-Hexamethyl 1,2,3,4-Tetrahydro Naphthalene (GANOLID)	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.	4 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008782AM24
RA File Number	092404000481 AM16
Licence No and Date	0910062849/10/11/2015

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Simeprevir Sodium	1 kg.	1	(2R,3aR,10Z,11aS,12aR,14aR)-2,3,3a,4,5,6,7,8,9,11a,12,13,14,14a-Tetradecahydro-2-[[7- methoxy-8-methyl-2-[4-(1-methylethyl)-2-thiazolyl]-4-quinolinyl]oxy]-5-methyl-4,14-dioxocyclopenta [c] cyclopropa [g][1,6]diazacyclotetradecine-12a(1H)-carboxylic acid	1.20 kg.

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

Case No.	5 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008734AM24
RA File Number	522404000036 AM18
Licence No and Date	5210042414/23/10/2017

Norms Committee Decision:

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

Case No.	6 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AETHER INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008733AM24
RA File Number	522404000016 AM19
Licence No and Date	5210042638/10/05/2018
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	7 / NC/3/MEET/Mar/202324/25
Case Status	Case Rejected
Party Name	PUROGENE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006886AM24
RA File Number	NA
Licence No and Date	0910067074/18/01/2019
Norms Committee Decision:	
The committee considered the request of firm and it was observed that the firm neither submitted their application in the Head of (Review of norms) nor paid composition fees of Rs.5000/-. Therefore, the committee decided to withdraw the application of the firm and advised to submit their application in the Head of review of Norms on DGFT Back Office Portal.	

Case No.	8 / NC/3/MEET/Mar/202324/25				
Case Status	Case Approved				
Party Name	AETHER INDUSTRIES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024				
HQ File Number	HQRNORM REVIW00008735AM24				
RA File Number	522404000085 AM19				
Licence No and Date	5210043000/19/03/2019				
Norms Committee Decision:					
Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/23 dated 19/02/2024 against advance authorization No. 5210043441 dated 16/06/2020, 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:-					

		2	TETRAHYDROFURAN	1.00 kg.
		3	2-CHLOROBENZONITRILE	1.235 kg.

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

Case No.	9 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	VDH ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008896AM24
RA File Number	052404000721 AM19
Licence No and Date	0510410010/20/03/2019
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. Percentage Yield of reaction 2. Stoichiometric balance on molar basis to arrive at the quantity of raw material asked. 3. Copy of authorized technical literature.	

Case No.	10 / NC/3/MEET/Mar/202324/25
Case Status	Case Rejected
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008627AM24
RA File Number	039404001134 AM19
Licence No and Date	0310829511/10/06/2019
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.	11 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	CONCORD BIOTECH LIMITED
Meeting Number	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024

and Date	
HQ File Number	HQRNORM REVIW00008666AM24
RA File Number	082404000101 AM20
Licence No and Date	0810145581/27/06/2019
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant documents from the firm.	

Case No.	12 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008636AM24
RA File Number	039404000496 AM20
Licence No and Date	0310831890/27/09/2019
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	13 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008637AM24
RA File Number	039404000497 AM20
Licence No and Date	0310831894/27/09/2019
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	14 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008587AM24
RA File Number	522404000007 AM21
Licence No and Date	5210043401/22/05/2020
Norms Committee Decision:	

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

- i. **Complete justification for higher norms asked for making the revised quantity.**
- ii. **Production/Consumption data for the three years certified by Chartered Accountant.**
- iii. **In Appendix-4E, the quantity of *NN Dimethyl Foramide* asked for is different from the license / application quantity and to give detailed justification of quantity requested for.**

Case No.	15 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	MAC-CHEM PRODUCTS (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008759AM24
RA File Number	NA
Licence No and Date	0311000187/15/12/2020

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Hydrocortisone Sodium Succinate for Injection((Lyophilised sterile Bulk))	1 kg.	1	HYDROCORTISON E IP/USP/EP	0.80 kg.

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

Case No.	16 / NC/3/MEET/Mar/202324/25
Case Status	Case Rejected
Party Name	MAHIMA LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008699AM24
RA File Number	05AA04029372 AM21
Licence No and Date	0511001191/09/02/2021

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.	17 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008904AM24
RA File Number	31AA04007907 AM21
Licence No and Date	3111000255/30/03/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
AMINO ETHYL PIPERAZINE (ORGANIC CHEMICAL)	1 kg	1	MONO ETHANOL AMINE	1.4186 kg.

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

Case No.	18 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	GARUDA CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008758AM24
RA File Number	03AA04031910 AM21
Licence No and Date	0311003270/22/04/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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MONOETHYLAMINE HYDROCHLORIDE (MEA-HCl) IN POWDER FORM	1 kg.	1	MONOETHYLAMINE 70 PERCENTAGE AQUEOUS SOLUTION IN LIQUID FORM IN ISO TANKS	0.793 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	19 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008736AM24
RA File Number	52AA04008175 AM22
Licence No and Date	5211001047/26/07/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	20 / NC/3/MEET/Mar/202324/25										
Case Status	Case Approved										
Party Name	AETHER INDUSTRIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024										
HQ File Number	HQRNORM REVIW00008737AM24										
RA File Number	52AA04012264 AM22										
Licence No and Date	5211001107/05/08/2021										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Sep/202324/14 dated 27/09/2023 against advance authorization No. 5210043358 dated 06/03/2020 , 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:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>ORGANO-INORGANIC COMPOUNDS, HETEROCYCLIC COMPOUNDS, NECLEIC ACIDS AND THEIR SALTS AND</td><td>1 kg.</td><td>1</td><td>1, 5 PENTANEDIOL</td><td>1.486 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ORGANO-INORGANIC COMPOUNDS, HETEROCYCLIC COMPOUNDS, NECLEIC ACIDS AND THEIR SALTS AND	1 kg.	1	1, 5 PENTANEDIOL	1.486 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
ORGANO-INORGANIC COMPOUNDS, HETEROCYCLIC COMPOUNDS, NECLEIC ACIDS AND THEIR SALTS AND	1 kg.	1	1, 5 PENTANEDIOL	1.486 kg.							

SULPHONAMIDES, DELTA-VALEROLACTONE				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	21 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM REVIW00008902AM24
RA File Number	31AX04000040 AM22
Licence No and Date	3111000876/14/01/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
AMINO ETHYL PIPERAZINE	1 kg.	1	MONO ETHANOL AMINE	1.4186 kg.
ETHYLENEDIAMINE	1 kg	2	MONO ETHANOL AMINE	1.06 kg.
		3	AMMONIA ANHYDROUS	0.294 kg.
DI ETHYLENE TRI AMINE	1 kg	4	MONO ETHANOL AMINE	1.184 kg.
		5	AMMONIA ANHYDROUS	0.165 kg.
PIPERAZINE	1 kg	6	MONO ETHANOL AMINE	1.481 kg.
AMINO ETHYL ETHANOL AMINE	1 kg	7	MONO ETHANOL AMINE	1.173 kg.

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

Case No.	22 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
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 request of firm for review of ad-hoc norms and it was decided to call for following information/documents from the firm:- Complete justification for higher norms asked for making the revised quantity. Production/Consumption data for the three years certified by Chartered Accountant. In Appendix-4E, the quantity of <i>NN Dimethyl Foramide</i> asked for is different from the license / application quantity and to give detailed justification of quantity requested for.	

Case No.	23 / NC/3/MEET/Mar/202324/25													
Case Status	Case Approved													
Party Name	AETHER INDUSTRIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024													
HQ File Number	HQRNORM REVIW00008738AM24													
RA File Number	52AX04000220 AM23													
Licence No and Date	5211002594/03/06/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/23 dated 19/02/2024 against advance authorization No5210043427 dated 09/06/2020 , 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:-														
<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">ORGANIC-AROMATIC ETHERS AND THEIR HALOGENATED, SULPHONATED, NITRATED OR NITROSATED DERIVATES: 2-METHOXY-6-CHLOROTOLUENE</td><td rowspan="2">1 kg.</td><td>1</td><td>2, 6 DICHLOROTOLUENE</td><td>1.42 kg.</td></tr><tr><td>2</td><td>DIMETHYLSULFOXIDE</td><td>0.66 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ORGANIC-AROMATIC ETHERS AND THEIR HALOGENATED, SULPHONATED, NITRATED OR NITROSATED DERIVATES: 2-METHOXY-6-CHLOROTOLUENE	1 kg.	1	2, 6 DICHLOROTOLUENE	1.42 kg.	2	DIMETHYLSULFOXIDE	0.66 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
ORGANIC-AROMATIC ETHERS AND THEIR HALOGENATED, SULPHONATED, NITRATED OR NITROSATED DERIVATES: 2-METHOXY-6-CHLOROTOLUENE	1 kg.	1	2, 6 DICHLOROTOLUENE	1.42 kg.										
		2	DIMETHYLSULFOXIDE	0.66 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	24 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	GUJARAT FLUOROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006792AM24
RA File Number	NA
Licence No and Date	3411002592/29/07/2022

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.
PENTAFLUOROETHANE (HFC-125) PENTAFLUOROETHANE,R125, ISO TANK	1.0 MT	1	METHANOL IN BULK	0.729 MT
		2	Fluorspar Containing by weight more than 97 Percent of calcium fluoride	2.809 MT
		3	CHLOROFORM	0.330 MT
		4	SILICA GEL IMPORTED MODEL FNG-1	0.0003 MT
		5	SILICA GEL MODEL-A	0.00007 MT
		6	ALUMINA CATALYST 55659368	0.00005 MT
		7	TRIBUTYLAMINE	0.04 MT

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

Case No.	25 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ARCH PROTECTION CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024

HQ File Number	HQRNORM APPLY 00007396AM24
RA File Number	NA
Licence No and Date	0311021465/15/02/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	26 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006570AM24
RA File Number	03AX04003275 AM24
Licence No and Date	0311028379/01/11/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along relevant documents from the firm.	

Case No.	27 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006571AM24
RA File Number	03AX04003274 AM24
Licence No and Date	0311028380/01/11/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along relevant documents from the firm.	

Case No.	28 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006591AM24
RA File Number	03AX04003361 AM24
Licence No and Date	0311028403/02/11/2023
Norms Committee Decision:	

The Committee considered the case as per agenda and it was decided to call the firm for attending **Personal Hearing** before Norms Committee to explain its case along relevant documents from the firm.

Case No.	29 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006592AM24
RA File Number	03AX04003362 AM24
Licence No and Date	0311028404/02/11/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along relevant documents from the firm.	

Case No.	30 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006595AM24
RA File Number	08AX04001379 AM24
Licence No and Date	0811009841/02/11/2023

Norms Committee Decision:

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.
Opipramol Dihydrochloride Tablets 50 MG (OPIPRAMOL HEUMANN 50 MG)(Each film coated tablet contains: Opipramol Dihydrochloride 50 mg Excipient..q.s. Net content of active ingredient Opipramol Dihydrochloride should not be less than 95.00 kgs in export product.)	1900000 Numbers	1	Opipramol Dihydrochloride	96.9 kg.
Opipramol Dihydrochloride Tablets 100	980000	2	Opipramol Dihydrochloride	100.00 kg.

MG (OPIPRAMOL HEUMANN 100 MG)(Each film coated tablet contains: Opipramol Dihydrochloride 100 mg Excipients...q.s. Net content of active ingredient Opipramol Dihydrochloride should not be less than 98.000 kgs in export product.)	Numbers			
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RA concerned may take further necessary action as per above decision of NC.

Case No.	31 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006596AM24
RA File Number	08AX04001392 AM24
Licence No and Date	0811009842/02/11/2023

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.
Metamizole Sodium, Pitofenone Hydrochloride & Fenpiverinium Bromide Tablets. (Spasmalin Tablets 500mg).(Each coated tablet contains 500 MG of Metamizole Sodium B P mg Excipients...as per q.s. Net content of Metamizole Sodium B P should not be less than 9000.00 kg in export item.)	1800000 Numbers	1	Metamizole Sodium B. P.	9180 kg.
Metamizole Sodium, Pitofenone Hydrochloride & Fenpiverinium Bromide Tablets. (Spasmalin Tablets 500mg).(Each coated tablet contains 500 MG of Metamizole Sodium B P mg Excipients...as per q.s. Net content of Metamizole Sodium B P should not be	10000000 Numbers	2	Metamizole Sodium B. P.	5100 kg.

less that 5000.00 kg in export item.)				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	32 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006599AM24
RA File Number	03AX04003360 AM24
Licence No and Date	0311028414/02/11/2023
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 relevant documents from the firm.	

Case No.	33 / NC/3/MEET/Mar/202324/25													
Case Status	Case Approved													
Party Name	YASHO INDUSTRIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024													
HQ File Number	HQRNORM APPLY 00006624AM24													
RA File Number	03AX04003548 AM24													
Licence No and Date	0311028480/03/11/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Feb/202324/23 dated 19/02/2024 against advance authorization No. 0311029216 dated 26/10/2023 , 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:-														
<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">2,5-bis-(Tert-Nonyldithio)-1,3,4,-thiadizole(YALUB DM -113)(2,5-bis-(Tert-Nonyldithio)-1,3,4,-thiadizole (YALUB DM -113))</td><td rowspan="2">1 kg.</td><td>1</td><td>HYDRAZINE HYDRATE 80% (H.H)</td><td>0.134 kg.</td></tr><tr><td>2</td><td>CARBON DISULPHIDE</td><td>0.3502 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	2,5-bis-(Tert-Nonyldithio)-1,3,4,-thiadizole(YALUB DM -113)(2,5-bis-(Tert-Nonyldithio)-1,3,4,-thiadizole (YALUB DM -113))	1 kg.	1	HYDRAZINE HYDRATE 80% (H.H)	0.134 kg.	2	CARBON DISULPHIDE	0.3502 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
2,5-bis-(Tert-Nonyldithio)-1,3,4,-thiadizole(YALUB DM -113)(2,5-bis-(Tert-Nonyldithio)-1,3,4,-thiadizole (YALUB DM -113))	1 kg.	1	HYDRAZINE HYDRATE 80% (H.H)	0.134 kg.										
		2	CARBON DISULPHIDE	0.3502 kg.										

		3	TERT -NONYL MERCAPTAN (S-MERCAPTAN)	0.700 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	34 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006633AM24
RA File Number	03AX04003515 AM24
Licence No and Date	0311028487/04/11/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	35 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006646AM24
RA File Number	34AX04000591 AM24
Licence No and Date	3411004295/06/11/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. Copy of Master Batch Formula showing net content of all inputs in the export products.	

Case No.	36 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	COPMED PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006677AM24
RA File Number	05AX04002347 AM24
Licence No and Date	0511021908/07/11/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Moxikind-CV 375 Tablets (Amoxicillin and Potassium Clavulanate Tablets BP 250/125 mg)	1 Number	1	CLAVULANATE POTASSIUM + MICRO CRYSTALLINE CELLULOSE (1:1) I.P. / EP / USP	303.773 mg.
Moxikind-CV 625 Tablets (Amoxicillin and Potassium Clavulanate Tablets BP 500/125 mg)	1 Number	2	CLAVULANATE POTASSIUM + MICRO CRYSTALLINE CELLULOSE (1:1) I.P. / EP / USP	303.773 mg.
Moxikind-CV 1000 Tablets (Amoxicillin and Potassium Clavulanate Tablets BP 875/125 mg)	1 Number	3	CLAVULANATE POTASSIUM + MICRO CRYSTALLINE CELLULOSE (1:1) I.P. / EP / USP	303.773 mg.
Moxikind-CV 457 (Amoxicillin and Potassium Clavulanate Oral suspension BP 400/57 mg each 5ml) 100 ML	1 Number	4	CLAVULANATE POTASSIUM + SILICON DIOXIDE (1:1) I.P. / EP / USP	2828.386 mg.
Moxikind-CV 228.5 (Amoxicillin and Potassium Clavulanate Oral suspension BP 200/28.5 mg each 5ml) 100 ML	1 Number	5	CLAVULANATE POTASSIUM + SILICON DIOXIDE (1:1) I.P. / EP / USP	1414.193 mg

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

Case No.	37 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006682AM24
RA File Number	34AX04000610 AM24
Licence No and Date	3411004316/07/11/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 5 gm Tube(Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 5 gm Tube (Net content of active ingredients 125.00 kgs and 125.00 kgs))	1000000 Numbers	1	Lidocaine USP	127.49 kg.
		2	Prilocaine Base USP	127.49 kg.
Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 30 gm tube(Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 30 gm tube (Net content of active ingredients 862.500 kgs and 862.500 kgs))	1150000 Numbers	3	Lidocaine USP	879.74 kg.
		4	Prilocaine Base USP	879.74 kg.
Lidocaine Ointment USP 5% 30 gm tube(Lidocaine Ointment USP 5% 30 gm tube (Net content of active ingredients 7.5 kgs))	5000 Numbers	5	Lidocaine USP	7.64 kg.
Lidocaine Ointment USP 5% 35.44 gm tube(Lidocaine Ointment USP 5% 35.44 gm tube (Net content of active ingredients 8.86 kgs))	5000 Numbers	6	Lidocaine USP	9.03 kg.
Lidocaine Ointment USP 5% 50 gm jar(Lidocaine Ointment USP 5% 50 gm jar (Net content of active ingredients 12.50 kgs))	5000 Numbers	7	Lidocaine USP	12.74 kg.

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

Case No.	38 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	PLAKSHA INDUSTRIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024

HQ File Number	HQRNORM APPLY 00006683AM24			
RA File Number	08AX04001504 AM24			
Licence No and Date	0811009884/07/11/2023			
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.
LAUROYL CHILORIDE (LAUROYL CHILORIDE NET CONTENT OF EXPORT PRODUCT - LAURIC ACID IS 96000.00 KGS)	1 kg.	1	LAURIC ACID	0.925 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	39 / NC/3/MEET/Mar/202324/25			
Case Status	Case Approved			
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024			
HQ File Number	HQRNORM APPLY 00006696AM24			
RA File Number	08AX04001328 AM24			
Licence No and Date	0811009658/07/11/2023			
Norms Committee Decision:				
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

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

Case No.	40 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006698AM24
RA File Number	08AX04001495 AM24
Licence No and Date	0811009892/07/11/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)(Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL))	65220 Numbers	1	Tranexamic acid	68.481 kg.

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

Case No.	41 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006699AM24
RA File Number	08AX04001494 AM24
Licence No and Date	0811009893/07/11/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)(Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL))	86960 Numbers	1	Tranexamic acid	91.308 kg.

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

Case No.	42 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006734AM24
RA File Number	34AX04000582 AM24
Licence No and Date	3411004327/08/11/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Aldehyde C10 (Capric Aldehyde)	1 kg.	1	Fatty Alcohol C10 98	1.066 kg.

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

Case No.	43 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006759AM24
RA File Number	03AX04003628 AM24

Licence No and Date	0311028603/08/11/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jan/202324/231 dated 24/01/2024 against advance authorization No. 0311029329 dated 14/12/2023 , 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.
Atorvastatin Calcium Tablets USP 10mg((Net Content of Import Sr. No. 1 is 308.205 kgs, Sr. No. 2 is 1743.606 kg, Sr. No. 3 is 487.323 kg, Sr. No. 4 is 303000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg.
		2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg.
		3	Calcium Acetate	18.049 mg.
		4	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy.
Atorvastatin Calcium Tablets USP 20 mg((Net Content of Import Sr. No. 1 is 205.470 kgs, Sr. No. 2 is 1164.843 kg, Sr. No. 3 is 324.810 kg, Sr. No. 4 is 101000 Nos.))	1 Number Tablet	5	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg.
		6	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427 mg.
		7	Calcium Acetate	36.090 mg.
		8	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy.
Atorvastatin Calcium Tablets USP 40mg((Net Content of Import Sr. No. 1 is 3857.337 kgs, Sr. No. 2 is 21833.568 kg, Sr. No. 3 is 6088.070 kg, Sr. No. 4 is 949400 Nos.))	1 Number Tablet	9	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg.
		10	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08 mg.

Atorvastatin Calcium Tablets USP 80mg((Net Content of Import Sr. No. 1 is 2052.000 kgs, Sr. No. 2 is 11659.635 kg, Sr. No. 3 is 3260.903 kg, Sr. No. 4 is 252500 Nos.))	1 Number Tablet	11	Calcium Acetate	71.963 mg
		12	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy.
		13	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg.
		14	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg.
		15	Calcium Acetate	144.929 mg.
		16	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy.

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

- 1. Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application) of Apotex Corp, US. Agend for Apotex Inc., Canada.**
- 2. Export to USA only.**
- 3. Firm holding Certificate of Manufacturing Exclusively.**

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

Case No.	44 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006764AM24
RA File Number	08AX04001484 AM24
Licence No and Date	0811009927/09/11/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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CLINDAMYCIN PHOSPHATE TOPICAL SOLUTION USP 1% 30ML (EACH ML CONTAIN CLINDAMYCIN PHOSPHATE USP EQUIVALENT CLINDAMYCIN 10((ACTIVE INGREDIENT: CLINDAMYCIN PHOSPHATE USP EQUIVALENT TO CLINDAMYCIN - NET WT. 94.988 KGS))	1 Number	1	CLINDAMYCIN PHOSPHATE USP	363.50 mg.
		2	BOTTLE 10Z ROUND WHITE OPAQU HDPE JERHEL PT	Relevant, as per packing policy
		3	CLOSURE 24MM WHITE PP SG75 MOLDRITE	Relevant, as per packing policy
		4	CLOSURE 24MM WHITE STEP UP & APP DAB O MATIC	Relevant, as per packing policy
CLINDAMYCIN PHOSPHATE TOPICAL SOLUTION USP 1% 60ML (EACH ML CONTAIN CLINDAMYCIN PHOSPHATE USP EQUIVALENT CLINDAMYCIN 10((ACTIVE INGREDIENT: CLINDAMYCIN PHOSPHATE USP EQUIVALENT TO CLINDAMYCIN - NET WT. 414.996 KGS))	1 Number	5	CLINDAMYCIN PHOSPHATE USP	727.20 mg.
		6	BOTTLE 20Z ROUN WHITE OPAQUE HDPE JERHEL PT	Relevant, as per packing policy
		7	CLOSURE 24MM WHITE PP SG75 MOLDRITE	Relevant, as per packing policy
		8	CLOSURE 24MM WHITE STEP UP & APP DAB O MATIC	Relevant, as per packing policy

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

Case No.	45 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006765AM24
RA File Number	08AX04001483 AM24
Licence No and Date	0811009928/09/11/2023
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CLINDAMYCIN PHOSPHATE GEL USP 1% 30GM (EACH GRAM CONTAIN CLINDAMYCIN PHOSPHATE USP EQUIVALENT CLINDAMYCIN 10 MG) ((ACTIVE INGREDIENT: CLINDAMYCIN PHOSPHATE USP EQUIVALENT TO CLINDAMYCIN - NET WT. 84.998 KGS))	283325 Numbers	1	CLINDAMYCIN PHOSPHATE USP	103.022 kg.
CLINDAMYCIN PHOSPHATE GEL USP 1% 60GM (EACH GRAM CONTAIN CLINDAMYCIN PHOSPHATE USP EQUIVALENT CLINDAMYCIN 10 MG) ((ACTIVE INGREDIENT: CLINDAMYCIN PHOSPHATE USP EQUIVALENT TO CLINDAMYCIN - NET WT. 114.990 KGS))	191650 Numbers	2	CLINDAMYCIN PHOSPHATE USP	139.374 kg.

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

Case No.	46 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006766AM24
RA File Number	08AX04001473 AM24
Licence No and Date	0811009930/09/11/2023
Norms Committee Decision:	
The committee considered the case as per agenda and it was decided to fix ad-hoc norms as per SION A-412 .	

Case No.	47 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred

Party Name	RALLIS INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006775AM24
RA File Number	03AX04003377 AM24
Licence No and Date	0311028623/09/11/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	48 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AKUMS DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006789AM24
RA File Number	05AX04002288 AM24
Licence No and Date	0511022010/09/11/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
Copy of Drug Manufacturing Licence (DML) showing approved composition of export item.	

Case No.	49 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006797AM24
RA File Number	05AX04002297 AM24
Licence No and Date	0511022013/10/11/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
i. 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.	

Case No.	50 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006801AM24
RA File Number	52AX04000234 AM24
Licence No and Date	5211006397/10/11/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	51 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006807AM24
RA File Number	34AX04000624 AM24
Licence No and Date	3411004346/10/11/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
Copy of Master Batch Formula for each export item.	

Case No.	52 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006809AM24
RA File Number	05AX04002413 AM24
Licence No and Date	0511022034/10/11/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. Copy of Drug Manufacturing License (DML) for the export item. 2. Material Balance for entire process showing wastage of API in each step.	

Case No.	53 / NC/3/MEET/Mar/202324/25
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Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006827AM24
RA File Number	03AX04003708 AM24
Licence No and Date	0311028699/13/11/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
OCTYLATED DIPHENYLAMINE (OCD FLAKES/POWDER)	1 kg.	1	DIPHENYLAMINE	0.405 kg.
		2	DI ISOBUTYLENE	0.622 kg.
		3	ACTIVATED CLAY	0.10 kg.

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

Case No.	54 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006837AM24
RA File Number	09AX04000734 AM24
Licence No and Date	0911006227/14/11/2023

Norms Committee Decision:

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

- i. **Complete and Balanced chemical reactions, molar weight and percentage yield on molar basis, for each step.**
- ii. **Production/Consumption data for last three years duly certified by GST Authorities.**

Case No.	55 / NC/3/MEET/Mar/202324/25
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Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006838AM24
RA File Number	09AX04000733 AM24
Licence No and Date	0911006228/14/11/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- i. Complete and Balanced chemical reactions, molar weight and percentage yield on molar basis, for each step. ii. Production/Consumption data for last three years duly certified by GST Authorities.	

Case No.	56 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AKUMS DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006849AM24
RA File Number	05AX04001479 AM23
Licence No and Date	0511021951/15/11/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Copy of Drug Manufacturing License (DML) showing approved composition of export item. 2. Certificate of Analysis (CoA) of import item from foreign supplier.	

Case No.	57 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	RECKITT BENCKISER (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006851AM24
RA File Number	05AX04002451 AM24
Licence No and Date	0511022069/15/11/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Sep/202324/13 dated 14/09/2023 against advance authorization No. 0511019590 dated 30/06/2023, 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:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DISPRIN DIRECTS /MELTS ((ASPIRIN PH.EUR 300MG) ACETYL SALICYLIC ACID 300 mg Tablet (ASPIRIN))	1 Number Tablet	1	SACCHARIN BASE 55Ox	1.00 mg.
		2	GLYCINE EP	133.30 mg.
DISPRIN CARDIOCARE((ASPIRIN BP 100MG) ACETYL SALICYLIC ACID 100 mg Tablet (ASPIRIN))	1 Number Tablet	3	SACCHARIN BASE 55Ox	0.334 mg.
		4	GLYCINE EP	44.40 mg.

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

Case No.	58 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006857AM24
RA File Number	03AX04003687 AM24
Licence No and Date	0311028732/16/11/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

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

Case No.	59 / NC/3/MEET/Mar/202324/25
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Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006896AM24
RA File Number	08AX04001535 AM24
Licence No and Date	0811009983/17/11/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Copy of Drug Manufacturing Licence (DML) showing vial size of each export item.	

Case No.	60 / NC/3/MEET/Mar/202324/25	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024	
HQ File Number	HQRNORM APPLY 00006908AM24	
RA File Number	03AX04003714 AM24	
Licence No and Date	0311028792/20/11/2023	
Norms Committee Decision:		
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms for export to US only are as under:-		
Sl. No	Export Product	Quantity
1	Medical Creams and Ointments(CICLOPIROX SOLUTION TOPICAL 8% 6.6ML Tot WT 1980Kgs. (Net Cont : Ciclopirox 158.40Kgs, Isoprop 613.80Kg, Ethyl ace 613.80Kgs, Buty est 594Kgs, Glass bottle 300000 Nos, brush 300000 Nos, Cap ribb 300000 Nos))	1 Number
S. No	Import Product	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 3% wastage.
2	Relevant Excipients	Net content in the export product plus 3% wastage.

3	Relevant Packaging Material	Relevant as per Packing Policy
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Note:

i. 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**

ii. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**

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

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

Case No.	61 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	LINCOLN PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006918AM24
RA File Number	08AX04001563 AM24
Licence No and Date	0811009996/20/11/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ALENDRONATE SODIUM TABLETS USP 70 MG (PACKING 1x4 = 4 NOS IN EACH PACK.)(TOTAL SODIUM ALENDRONATE TRIHYDRATE USED i.e. 206000 x 91.37 / 1000000=18.82 KG NET))	1 Number	1	SODIUM ALENDRONATE TRIHYDRATE	93.20 mg.

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

Case No.	62 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006944AM24
RA File Number	03AX04003747 AM24
Licence No and Date	0311028819/21/11/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jun/202324/6 dated 14/06/2023** against advance authorization **No. 0311021244 dated 08/02/2023**, 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.
METHYL PARABEN	1 kg.	1	PARAHYDROXY BENZOIC ACID	0.97 kg.
		2	METHANOL	0.50 kg.

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

Case No.	63 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	GELTEC PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006949AM24
RA File Number	03AX04003778 AM24
Licence No and Date	0311028827/21/11/2023

Norms Committee Decision:

The Committee considered the case as per agenda and it has been observed that the matter pertains to Norms Committee-6, therefore, it has been decided to refer the case to **Norms Committee-6** for further necessary action at

their end.

Case No.	64 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006966AM24
RA File Number	08AX04001564 AM24
Licence No and Date	0811010011/22/11/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	65 / NC/3/MEET/Mar/202324/25													
Case Status	Case Approved													
Party Name	ASTEC LIFESCIENCES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024													
HQ File Number	HQRNORM APPLY 00006975AM24													
RA File Number	03AX04003793 AM24													
Licence No and Date	0311028844/22/11/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202223/20 dated 24/02/2023 against advance authorization No. 0311013033 dated 17/03/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">DEXTRINOL</td><td rowspan="2">1 kg.</td><td>1</td><td>CROTONIC ACID</td><td>0.849 kg.</td></tr><tr><td>2</td><td>BUTADIENE</td><td>0.629 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DEXTRINOL	1 kg.	1	CROTONIC ACID	0.849 kg.	2	BUTADIENE	0.629 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
DEXTRINOL	1 kg.	1	CROTONIC ACID	0.849 kg.										
		2	BUTADIENE	0.629 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	66 / NC/3/MEET/Mar/202324/25
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Case Status	Case Deferred
Party Name	MEDICLONE HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006991AM24
RA File Number	04AX04000678 AM24
Licence No and Date	0411006454/22/11/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- I. Certificate of Analysis (CoA) of import item from Foreign Supplier II. Bill of Entry for import item.	

Case No.	67 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00006994AM24
RA File Number	03AX04003758 AM24
Licence No and Date	0311028853/23/11/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Justification of low yield of 27.88% in first stage with any documentary evidence such as any patent process.	

Case No.	68 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007003AM24
RA File Number	03AX04003781 AM24
Licence No and Date	0311028861/23/11/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jul/202324/9 dated 28/07/2023 against advance authorization No. 0310819230 dated 19/02/2018, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sodium Lactate (Hartmann's) 1000ml AUS	1 Number	1	SODIUM LACTATE (PURASAL SP/F 50)(EP)	Net content in export + 2% wastage.
		2	POTASSIUM CHLORIDE EP	Net content in export + 2% wastage.
		3	CALCIUM CHLORIDE EP	Net content in export + 2% wastage.
		4	Sodium Chloride (SANAL) (EP)	Net content in export + 2% wastage.
		5	SF9-11 195/140 (PLASTIC FILM (NON-PVC) FOR PRIMARY PACKING) (0369631)	Net content in export + 1% wastage.
		6	OFR2-11 120/524 PHTALATFREE (PLASTIC FILM (NON-PVC) FOR SECONDARY PACKING (0369681)	Net content in export + 1% wastage.
		7	UFR2-11 150/524 PHTALATFREE (PLASTIC FILM (NON-PVC) FOR SECONDARY PACKING (0369661)	Net content in export + 1% wastage.
		8	SSC Infusion Port (0434181)	Net content in export + 1% wastage.
		9	SSC Injection Port (Art. 0434371)	Net content in export + 1% wastage.
		10	BOP Infusion Port (Art.No 0434171)	Net content in export + 1% wastage.
		11	BOP Injection Port (Art. 0434481)	Net content in export + 1% wastage.

		12	Hot Stamping foil (Art. 0368991)	Net content in export + 1% wastage.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	69 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007004AM24
RA File Number	03AX04003819 AM24
Licence No and Date	0311028867/23/11/2023

Norms Committee Decision:

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

Sl. No	Export Product	Quantity
1	Medical Creams and Onitments (Fluorouracil Topical Solution USP 5%, 10ml)	1 Number

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

Note:

- i. 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**

ii. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US**.

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

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

Case No.	70 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	PRACHI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007007AM24
RA File Number	03AX04003817 AM24
Licence No and Date	0311028871/23/11/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No.0311023358 dated 04/05/2023**, 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.
THIAMINE HYDROCHLORIDE	1 kg.	1	THIAMINE MONONITRATE	0.922

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

Case No.	71 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007029AM24
RA File Number	03AX04003854 AM24

Licence No and Date	0311028907/24/11/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	72 / NC/3/MEET/Mar/202324/25			
Case Status	Case Approved			
Party Name	UNIMAX LABORATORIES			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024			
HQ File Number	HQRNORM APPLY 00007035AM24			
RA File Number	05AX04002563 AM24			
Licence No and Date	0511022259/24/11/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Spiramycin Tablets 1.5 MIU (Each tablet contains Spiramycin EP)	1 Number	1	Spiramycin EP	373.02 mg.
Azithromycin Tablets 250 mg USP (Each tablet contains : Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	2	Azithromycin Dihydrate USP	267.27 mg.

Azithromycin Tablets 500 mg USP (Each tablet contains : Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	3	Azithromycin Dihydrate USP	534.54 mg.
Azithromycin Tablets 250 mg IP(Each tablet contains : Azithromycin IP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	4	Azithromycin Dihydrate IP	267.27 mg.
Azithromycin Tablets 500 mg IP(Each tablet contains : Azithromycin IP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	5	Azithromycin Dihydrate IP	534.54 mg.

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

Case No.	73 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007038AM24
RA File Number	07AX04001334 AM24
Licence No and Date	0711009791/24/11/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Complete Chemical reaction, indicating molecular weight of reactant/s and product/s with overall yield of the reaction for both the export items. 2. Production specifically for both the export items vis a vis consumption of raw materials for the last three years duly certified by Chartered Accountant. 3. A copy of minutes of norms committee, if approved in the past.	

Case No.	74 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024

HQ File Number	HQRNORM APPLY 00007039AM24
RA File Number	07AX04001335 AM24
Licence No and Date	0711009794/24/11/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Complete Chemical reaction, indicating molecular weight of reactant/s and product/s with overall yield of the reaction for both the export items. Production specifically for both the export items viz-a-viz consumption of raw materials for the last three years duly certified by Chartered Accountant. A copy of minutes of norms committee, if approved in the past.	

Case No.	75 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007114AM24
RA File Number	07AX04001360 AM24
Licence No and Date	0711009823/30/11/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	76 / NC/3/MEET/Mar/202324/25					
Case Status	Case Approved					
Party Name	YASHO INDUSTRIES LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024					
HQ File Number	HQRNORM APPLY 00007126AM24					
RA File Number	03AX04003953 AM24					
Licence No and Date	0311029026/30/11/2023					
Norms Committee Decision:						
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-						
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.		

OCTYLATED DIPHENYLAMINE (OCD FLAKES/POWDER)	1 kg.	1	DIPHENYLAMINE	0.405 kg.
		2	DI ISOBUTYLENE	0.622 kg.
		3	ACTIVATED CLAY	0.10 kg.

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

Case No.	77 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007132AM24
RA File Number	34AX04000670 AM24
Licence No and Date	3411004394/30/11/2023

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/23 dated 19/02/2024** against advance authorization **No.3411004140 dated 21/09/2023** , 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.
Amantadine Hydrochloride capsules USP 100mg (Net content of active ingredients 300.00 kgs)	1 Number Capsule	1	Amantadine Hydrochloride USP	102.00 mg.
		2	Microcrystalline cellulose (Avicel PH301)	106.00 mg.
		3	Hydroxypropyl Cellulose (Klucel LF)	2.00 mg.
		4	Croscarmellose Sodium (Ac-Di-Sol)	10.00 mg.

		5	Colloidal Silicon Dioxide (Aerosil 200 Pharma)	1.00 mg.
		6	Magnesium Stearate (Vegetable Source)	1.00 mg.
Amantadine Hydrochloride Tablets USP 100mg (Net content of active ingredients 350.00 kgs)	1 Number Tablet	7	Amantadine Hydrochloride USP	102.00 mg.
		8	Microcrystalline Cellulose (Avicel PH 101)	33.65 mg.
		9	Povidone (Kollidon 90F)	3.00 mg.
		10	Lake Pigment HT 5285 FD&C Yellow 6 Sunset Yellow FCF Aluminum Lake	0.300 mg
		11	Sodium Starch Glycolate (Type A) (EXPLOTAB)	4.50 mg.
		12	Povidone (K-30)	3.00 mg.
		13	Colloidal Silicon Dioxide (Aerosil 200 Pharma)	0.75 mg.
		14	Magnesium Stearate	0.80 mg.

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

Case No.	78 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007137AM24
RA File Number	07AX04001359 AM24
Licence No and Date	0711009827/01/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Mar/202324/25 dated 11/03/2024** against advance authorization **No.0711009827 dated 01/12/2023**, 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.
NORTRIPTYLINE HCL(IP/BP/USP)	1 kg.	1	1 BROMO 3 CHLORO PROPANE	0.96 kg.
		2	TETRA HYDRO FURAN	0.71 kg.
		3	ACETONE	1.00 kg.
		4	TOLUENE	1.00 kg.

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

Case No.	79 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007138AM24
RA File Number	07AX04001361 AM24
Licence No and Date	0711009828/01/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Apr/202223/1 dated 29/04/2022** against advance authorization **No.0711001528 dated 22/07/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CYCLOBENZAPRINE HCL(USP)	1 kg.	1	1 BROMO 3 CHLORO PROPANE	0.95 kg.

		2	TETRA HYDRO FURAN	0.25 kg.
		3	ACETONE	0.75 kg.

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

Case No.	80 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007145AM24
RA File Number	07AX04001362 AM24
Licence No and Date	0711009832/01/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Mar/202223/24 dated 13/04/2023** against advance authorization **No.0711003633 dated 06/04/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CLOMIPRAMINE HCL(BP/EP/USP/JP)	1 kg.	1	1 BROMO 3 CHLORO PROPANE	0.85 kg.
		2	IMINODIBENZYL	1.00 kg.
		3	METHANOL	1.20 kg.
		4	IPA	0.50 kg.
		5	TOLUENE	0.50 kg.
		6	ACETONE	1.00 kg.

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

Case No.	81 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	PRASHI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007147AM24
RA File Number	03AX04003935 AM24
Licence No and Date	0311029047/01/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
COTRIMOXAZOLE TABLETS BP 480MG(COTRIMOXAZOLE TABLETS BP 480MG EACH TABLET CONTAINS: SULPHAMETHOXAZOLE BP 400MG TRIMETHOPRIM BP 80MG 340000 X 10 X 10T)	1 Number	1	SULPHAMETHOXAZOLE	408.00 mg.
		2	TRIMETHOPRIM	81.60 mg.
DAVITRIM FORT TABLETS(DAVITRIM FORT TABLETS EACH TABLET CONTAINS : SULPHAMETHOXAZOLE BP 800MG TRIMETHOPRIM BP 160MG 80000 X 10 X 1 X 10T)	1 Number	3	SULPHAMETHOXAZOLE	816.00 mg.
		4	TRIMETHOPRIM	163.20 mg.

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

Case No.	82 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007165AM24
RA File Number	03AX04003897 AM24
Licence No and Date	0311029063/02/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

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

Case No.	83 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AARTI INDUSTRIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007168AM24
RA File Number	03AX04003918 AM24
Licence No and Date	0311029075/04/12/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	84 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007173AM24
RA File Number	05AX04002730 AM24
Licence No and Date	0511022438/04/12/2023
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
I. Please give details of weight of each pack of Progesterone Gel in line with DML given for export item No. 5 and 6. II. Detailed working for export item No. 5 and 6.	

Case No.	85 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007180AM24
RA File Number	03AX04003966 AM24
Licence No and Date	0311029092/04/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
COUMARIN	1 kg.	1	PHENOL	0.925 kg.
		2	XYLENE	0.026 kg.
		3	MAGNESIUM TURNING	0.148 kg.
		4	PARAFORMALDEHYDE	0.874 kg.
		5	ACETIC ANHYDRIDE	0.7356 kg.

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

Case No.	86 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007192AM24
RA File Number	34AX04000671 AM24
Licence No and Date	3411004398/04/12/2023
Norms Committee Decision:	

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

Case No.	87 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007193AM24
RA File Number	34AX04000676 AM24
Licence No and Date	3411004399/04/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Fluorouracil Injection USP 2.5 gm 50 ML(Fluorouracil Injection USP 2.5 gm 50 ML (Net content of active ingredients 625.00 kgs))	1 Number	1	Fluorouracil USP	2.60 gm.
Fluorouracil Injection USP 5 gm 100 ML(Fluorouracil Injection USP 5 gm 100 ML (Net content of active ingredients 750.00 kgs))	1 Number	2	Fluorouracil USP	5.20 gm.

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

Case No.	88 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007195AM24
RA File Number	34AX04000621 AM24
Licence No and Date	3411004402/04/12/2023

Norms Committee Decision:

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

Case No.	89 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	LARK LABORATORIES (INDIA) LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007198AM24
RA File Number	05AX04002725 AM24
Licence No and Date	0511022462/05/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
AMPICILLIN 1 GRAM TABLETS (AMPICILLIN 1 GRAM TABLET EACH TABLETS CONTAINING AMPICILLIN TRIHYDRATE EQUIVALENT TO 1 GRAM AMPICILLIN BASE.)	1 Number	1	AMPICILLIN TRIHYDRATE	1154 mg.

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

Case No.	90 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007200AM24
RA File Number	07AX04001353 AM24
Licence No and Date	0711009871/05/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
REBAMIPIDE 100MG TABLETS [5392.157 KG])	1 Number	1	REBAMIPIDE	102.00 mg.
		2	ETHYL ALCOHOL 200 PROOF	0.151 mg.

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

Case No.	91 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007203AM24
RA File Number	09AX04000735 AM24
Licence No and Date	0911006328/05/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Bivalirudin for Injection 250mg/Vial (Consists of 14.00 Kgs Bivalirudin)	1 Number Vial	1	Bivalirudin	262.50 mg.

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

Case No.	92 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007220AM24
RA File Number	03AX04003769 AM24
Licence No and	0311029140/06/12/2023

Date	
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	93 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007222AM24
RA File Number	03AX04003843 AM24
Licence No and Date	0311029142/06/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Sep/202223/22 dated 23/09/2022** against advance authorization **No. 0311005584 dated 23/07/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PROPYL PARABEN	1 kg.	1	PARAHYDROXY BENZOIC ACID	0.80 kg.
		2	N PROPANOL	0.347 kg.

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

Case No.	94 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007224AM24
RA File Number	03AX04003995 AM24
Licence No and Date	0311029148/06/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Isobornyl Cyclohexanol	1kg	1	Gum Turpentine Oil	1.582 kg.

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

Case No.	95 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007236AM24
RA File Number	03AX04003565 AM24
Licence No and Date	0311029156/06/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/23 dated 19/02/2024** against advance authorization **No.0311018798 dated 22/10/2022** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRIS NONYL PHENYL PHOSPHITE((TNPP))	1 kg.	1	NONYL PHENOL	1.066 kg.
		2	YELLOW PHOSPHORUS	0.0506 kg.

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

Case No.	96 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	UNIMAX CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007237AM24

RA File Number	03AX04003928 AM24													
Licence No and Date	0311029157/06/12/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No.0311013922 dated 18.04.2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table 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>Azithromycin Dihydrate (Tech. Spec.: Pharmacopeial Grade)</td> <td>1 Kg</td> <td>1</td> <td>Azithromycin Amine</td> <td>0.9434 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Azithromycin Dihydrate (Tech. Spec.: Pharmacopeial Grade)	1 Kg	1	Azithromycin Amine	0.9434 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Azithromycin Dihydrate (Tech. Spec.: Pharmacopeial Grade)	1 Kg	1	Azithromycin Amine	0.9434 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	97 / NC/3/MEET/Mar/202324/25													
Case Status	Case Approved													
Party Name	BROOKS STERISCIENCE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024													
HQ File Number	HQRNORM APPLY 00007260AM24													
RA File Number	34AX04000689 AM24													
Licence No and Date	3411004418/07/12/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No.3010105213 dated 02.06.2020 , 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:-														
<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>Meropenem Injection USP1000 mg.Each vial contains Sterile Meropenem Trihydrate USP equ to Anhydrous Meropenem1000mg (SterileSodium Carbonate USP equ to Sodium 90.2mg with Pre-Import condition in terms of Para 4.13(iii) of FTP 2015-20 import should be made 1st &EO shall be fulfilled within 12 months from the dt. of</td> <td>1 Number</td> <td>1</td> <td>MEROPENEM WITH SODIUM CARBONATE USP</td> <td>1.29 gm.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Meropenem Injection USP1000 mg.Each vial contains Sterile Meropenem Trihydrate USP equ to Anhydrous Meropenem1000mg (SterileSodium Carbonate USP equ to Sodium 90.2mg with Pre-Import condition in terms of Para 4.13(iii) of FTP 2015-20 import should be made 1st &EO shall be fulfilled within 12 months from the dt. of	1 Number	1	MEROPENEM WITH SODIUM CARBONATE USP	1.29 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Meropenem Injection USP1000 mg.Each vial contains Sterile Meropenem Trihydrate USP equ to Anhydrous Meropenem1000mg (SterileSodium Carbonate USP equ to Sodium 90.2mg with Pre-Import condition in terms of Para 4.13(iii) of FTP 2015-20 import should be made 1st &EO shall be fulfilled within 12 months from the dt. of	1 Number	1	MEROPENEM WITH SODIUM CARBONATE USP	1.29 gm.										

import of each consignment in terms of Appdix-4J)				
Export Item Name: Meropenem Injection 500 mg USPEach vial contains Sterile Meropenem Trihydrate USP equ to Anhydrous Meropenem 500mg (SterileSodium Carbonate USP equ to Sodium 90.2mg with Pre-Import condition in terms of Para 4.13(iii) of FTP 2015-20 import shud be made 1st &EO shall be fulfilled within 12 months from the dt. of import of each consignment in terms of Appdix-4J)	1 Number	2	MEROPENEM WITH SODIUM CARBONATE USP	0.645 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	98 / NC/3/MEET/Mar/202324/25													
Case Status	Case Approved													
Party Name	AMI LIFESCIENCES PVT LTD													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024													
HQ File Number	HQRNORM APPLY 00007264AM24													
RA File Number	34AX04000693 AM24													
Licence No and Date	3411004416/07/12/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Betahistine Dihydrochloride</td><td>1 kg.</td><td>1</td><td>Pyridine 2 Ethanol</td><td>0.931 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Betahistine Dihydrochloride	1 kg.	1	Pyridine 2 Ethanol	0.931 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Betahistine Dihydrochloride	1 kg.	1	Pyridine 2 Ethanol	0.931 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	99 / NC/3/MEET/Mar/202324/25			
Case Status	Case Approved			
Party Name	R.L.FINE CHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024			
HQ File Number	HQRNORM APPLY 00007283AM24			
RA File Number	07AX04001377 AM24			

Licence No and Date	0711009901/08/12/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CHLORPROMAZINE HYDROCHLORIDE (BP/EP/USP/IP)	1Kg	1	2 CHLORO PHENOTHIAZINE	0.95 kg
		2	1 BROMO 3 CHLORO PROPANE	0.90 kg
		3	TOLUENE	1.92 kg
		4	ACETONE	1.65 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	100 / NC/3/MEET/Mar/202324/25			
Case Status	Case Approved			
Party Name	OMEGA COLORS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024			
HQ File Number	HQRNORM APPLY 00007293AM24			
RA File Number	03AX04003836 AM24			
Licence No and Date	0311029233/08/12/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
INTRAVEOUS INFUSION /INJECTION 500ml (LIFEPORT NS 500ml)(Sodium Chloride Intravenous Solution BP	600000 Numbers	1	Caps and Closures for Bottles	Relevant as per packing policy with accountability.

(0.9% w/v))		4	Polypropylene Granules	Relevant as per packing policy with accountability.
INTRAVEOUS INFUSION/INJECTION 500ml (LIFEPORT DNS 500ml)(Glucose 5.0% w/v and Sodium Chloride 0.9% w/v Intravenous Infusion BP)	500000 Numbers	2	Caps and Closures for Bottles	Relevant as per packing policy with accountability.
		5	Polypropylene Granules	Relevant as per packing policy with accountability.
INTRAVEOUS INFUSION/INJECTION 500ml (LIFEPORT RL 500ml)(Compound Sodium Lactate IV Infusion BP (Ringer Lactate Solution for Intravenous Infusion BP))	500000 Numbers	3	Caps and Closures for Bottles	Relevant as per packing policy with accountability.
		6	Polypropylene Granules	Relevant as per packing policy with accountability.

Note: RA will work-out the requirement of Polypropylene Granules as per Packing Policy.

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

Case No.	101 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007302AM24
RA File Number	09AX04000794 AM24
Licence No and Date	0911006352/11/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Daptomycin for Injection 350mg/vial 1s USA (Consist of 50.75 Kgs Daptomycin)	145000 Numbers	1	Daptomycin	55.825 kg.

Daptomycin for Injection 500mg/vial (Consist of 250.00Kgs Daptomycin)	500000 Numbers	2	Daptomycin	275.00 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	102 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	S KANT HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007308AM24
RA File Number	03AX04004027 AM24
Licence No and Date	0311029247/11/12/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	103 / NC/3/MEET/Mar/202324/25													
Case Status	Case Approved													
Party Name	ANUH PHARMA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024													
HQ File Number	HQRNORM APPLY 00007325AM24													
RA File Number	03AX04004081 AM24													
Licence No and Date	0311029265/12/12/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No.0311014743 dated 17.05.2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<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">Erythromycin 11,12 Carbonate IP/BP/EP/USP</td><td rowspan="2">1 Kg</td><td>1</td><td>Erythromycin Thiocyanate</td><td>1.22 kg.A</td></tr><tr><td>2</td><td>Ethylene Carbonate</td><td>0.975 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	Erythromycin 11,12 Carbonate IP/BP/EP/USP	1 Kg	1	Erythromycin Thiocyanate	1.22 kg.A	2	Ethylene Carbonate	0.975 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed										
Erythromycin 11,12 Carbonate IP/BP/EP/USP	1 Kg	1	Erythromycin Thiocyanate	1.22 kg.A										
		2	Ethylene Carbonate	0.975 kg										

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

Case No.	104 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007327AM24
RA File Number	03AX04004105 AM24
Licence No and Date	0311029268/12/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Apr/202324/1 dated 28/04/2023** against advance authorization **No.0311020073 dated 16.12.2022** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GENTAMICIN EYE/EAR DROPS 10 ML((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.030GM NET WT OF BULK DRUG IS 4.140 KGS))	138000Vials	1	Gentamicin Sulphate	5.072 kg

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

Case No.	105 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007334AM24
RA File Number	03AX04004079 AM24
Licence No and Date	0311029276/12/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202324/19 dated 05.01.2024** against advance authorization No.

0311019783 dated 06.12.2022; it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export Product	Qty.	Import items	Qty. allowed
1	FLUCORT N SKIN CREAM 0.025% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 1.210 Kgs.)	322660 Packs	FLUOCINOLONE ACETONIDE BP	9.10 kg
2	FLUCORT SKIN CREAM 0.025% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 1.210 Kgs.)	322660 Packs		
3	FLUCORT SKIN CREAM 0.025% (Pack Size 10 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.605 Kgs.)	242000 Packs		
4	FLUCORT SKIN CREAM 0.025% (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 1.210 Kgs.)	968000 Packs		
5	FLUOCINOLONE CREAM (TDR) ET 0.025% (Pack Size 10 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	96800 Packs		
6	CYNOZET CREAM 0.025% (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	193600 Packs		
7	CYNOZET CREAM 0.025% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	64532 Packs		
8	SUPRICORT CREAM 0.025% (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.726 Kgs.)	580800 Packs		
9	SUPRICORT CREAM 0.025% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.726 Kgs.)	193596 Packs		
10	SUPRICORT CREAM 0.025% (Pack Size 250 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	3873 Packs		
11	SUPRICORT N CREAM 0.025% (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	193600 Packs		

12	SUPRICORT N CREAM 0.025% (Pack Size 15 gms) (Net Wt.of 64532 Packs FLUOCINOLONE ACETONIDE BP is 0.242Kgs.)		
13	Flucort C Cream 0.01% (Pack Size 15 gms) (Net Wt.of 63332 Packs FLUOCINOLONE ACETONIDE BP is 0.095 Kgs)		
14	FLUCORT C OINTMENT 0.025% (Pack Size 15 gms) (Net 161330 Packs Wt.of FLUOCINOLONE ACETONIDE BP is 0.605 Kgs.)		
15	GLENCORT GEL 0.025% (Pack Size 5 gms) (Net Wt.of 361600 Packs FLUOCINOLONE ACETONIDE BP is 0.452 Kgs.)		
16	GLENCORT GEL 0.025% (Pack Size 30 gms) (Net Wt.of 64535 Packs FLUOCINOLONE ACETONIDE BP is 0.484 Kgs.)		
17	FLUCORT MZ SKIN OINTMENT 0.01% (Pack Size 15 gms) 96798 Packs (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.145 Kgs.)		
RA concerned may take further necessary action as per above decision of NC			

Case No.	106 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007335AM24
RA File Number	03AX04004073 AM24
Licence No and Date	0311029277/12/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/23 dated 19/02/2024** against advance authorization **No.0311027272 dated 21/09/2023**, 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.
TETRAHYDROFURAN (PURITY 99%)	1 kg.	1	1.4 Butandiol (Purity Min. 95%)	1.42 kg.

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

Case No.	107 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007339AM24
RA File Number	03AX04004064 AM24
Licence No and Date	0311029280/12/12/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	108 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007341AM24
RA File Number	03AX04004117 AM24
Licence No and Date	0311029284/12/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Sep/202324/14 dated 27/09/2023** against advance authorization **No.0311026873 dated 04/09/2023**, 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.
Agomelatine Citric Acid Co-Crystal	1 kg.	1	(7-METHOXY 1 NAPHTHYL) ACETONITRILE	0.60 kg.

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

Case No.	109 / NC/3/MEET/Mar/202324/25
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Case Status	Case Approved
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007346AM24
RA File Number	09AX04000824 AM24
Licence No and Date	0911006368/12/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/23 dated 19/02/2024** against advance authorization **No.0911005810 dated 20.09.2023**, 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.
CARBIDOPA 12.5 MG LEVODOPA 50 MG TABLETS	1 Number	1	CARBIDOPA	12.75 mg
		2	LEVODOPA	51.00 mg
CARBIDOPA 25 MG LEVODOPA 100 MG TABLETS	1 Number	3	CARBIDOPA	25.50 mg
		4	LEVODOPA	102.00 mg

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

Case No.	110 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	ZIM LABORATORIES LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007349AM24
RA File Number	50AX04000067 AM24
Licence No and Date	5011001200/12/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jun/202223/5 dated 08/07/2022** against advance authorization **No.5011000169 dated 24.06.2021**, 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.
Doxyzim 100 (Doxycycline Capsules BP 100 mg)	1 Number	1	Doxycycline Hyclate CEP Grade	117.73 mg

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

Case No.	111 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007387AM24
RA File Number	09AX04000787 AM24
Licence No and Date	0911006373/13/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PARACETAMOL GRANULES DC GRADE 90%	1 Kg	1	PARA AMINO PHENOL	0.727 kg
		2	ACETIC ANHYDRIDE	0.682 kg

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

Case No.	112 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	SHARON BIO-MEDICINE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024																
HQ File Number	HQRNORM APPLY 00007402AM24																
RA File Number	03AX04004187 AM24																
Licence No and Date	0311029349/14/12/2023																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Dec/202324/19 dated 05/01/2024 against advance authorization No.0311020778 dated 18/01/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table 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">MICONAZOLE NITRATE</td> <td rowspan="2">1 kg.</td> <td>1</td> <td>Alpha-(2,4-Dichlorophenyl)-1H- Imidazole-1-Ethanol</td> <td>0.662 kg.</td> </tr> <tr> <td>2</td> <td>2,4,Dichloro Benzyl Chloride?</td> <td>0.504 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MICONAZOLE NITRATE	1 kg.	1	Alpha-(2,4-Dichlorophenyl)-1H- Imidazole-1-Ethanol	0.662 kg.	2	2,4,Dichloro Benzyl Chloride?	0.504 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
MICONAZOLE NITRATE	1 kg.	1	Alpha-(2,4-Dichlorophenyl)-1H- Imidazole-1-Ethanol	0.662 kg.													
		2	2,4,Dichloro Benzyl Chloride?	0.504 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	113 / NC/3/MEET/Mar/202324/25													
Case Status	Case Approved													
Party Name	DISTO PHARMACEUTICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024													
HQ File Number	HQRNORM APPLY 00007425AM24													
RA File Number	09AX04000809 AM24													
Licence No and Date	0911006387/15/12/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>MINOCYCLINE IR PELLETS 35% W/W(PELLETS)</td> <td>200 Kg</td> <td>1</td> <td>MINOCYCLINE</td> <td>70.7 Kg</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MINOCYCLINE IR PELLETS 35% W/W(PELLETS)	200 Kg	1	MINOCYCLINE	70.7 Kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
MINOCYCLINE IR PELLETS 35% W/W(PELLETS)	200 Kg	1	MINOCYCLINE	70.7 Kg										

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

Case No.	114 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007460AM24
RA File Number	03AX04004237 AM24
Licence No and Date	0311029470/19/12/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	115 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007461AM24
RA File Number	03AX04004235 AM24
Licence No and Date	0311029471/19/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.

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

Case No.	116 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved

Party Name	HARMAN FINOCHEM LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024													
HQ File Number	HQRNORM APPLY 00007462AM24													
RA File Number	03AX04004236 AM24													
Licence No and Date	0311029472/19/12/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Sacubitril+Calcium (Sacubitril Calcium)</td><td>1 kg.</td><td>1</td><td>2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPPA)</td><td>1.237 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPPA)	1.237 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPPA)	1.237 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	117 / NC/3/MEET/Mar/202324/25			
Case Status	Case Approved			
Party Name	KAWAKEN STERLING SURFACTANTS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024			
HQ File Number	HQRNORM APPLY 00007478AM24			
RA File Number	03AX04004180 AM24			
Licence No and Date	0311029499/20/12/2023			
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:-				

			(MEG)	
STEROCARE EGMS (Ethylene Glycol Monostearate)	57000 kg.	3	STEARIC ACID 1842 (triple pressed)	50342.4 kg.
		4	Mono Ethylene Glycol (MEG)	11257.5 kg.
STEROCARE GMS (GLYCEROL MONO STEARATE)	57000 kg.	5	STEARIC ACID 1842 (triple pressed)	46124.4 kg.

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

Case No.	118 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	CHEMIPRIME IMPEX PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007498AM24
RA File Number	03AX04004009 AM24
Licence No and Date	0311029541/20/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cycloaliphatic amine ((Epocure HD 1618))	1 kg.	1	Epoxy Hardener	0.5025 kg.
		2	Benzyl Alcohol	0.3015 kg.
		3	Liquid Epoxy Resin	0.201 kg.

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

Case No.	119 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007500AM24
RA File Number	03AX04004231 AM24
Licence No and Date	0311029543/20/12/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Import item No. 9 does not match with export item No.6 as claimed in the application. 2. Justification/Amendment may be furnished.	

Case No.	120 / NC/3/MEET/Mar/202324/25										
Case Status	Case Approved										
Party Name	ANUH PHARMA LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024										
HQ File Number	HQRNORM APPLY 00007501AM24										
RA File Number	03AX04004051 AM24										
Licence No and Date	0311029544/20/12/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jan/202324/21 dated 24/01/2024 against advance authorization No.0311023591 dated 15/05/2023 , 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>Triamcinolone Acetonide IP/BP/USP/EP</td><td>1 kg.</td><td>1</td><td>9'11B-Epoxidetriamcinolone(5TR)</td><td>1.00 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Triamcinolone Acetonide IP/BP/USP/EP	1 kg.	1	9'11B-Epoxidetriamcinolone(5TR)	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Triamcinolone Acetonide IP/BP/USP/EP	1 kg.	1	9'11B-Epoxidetriamcinolone(5TR)	1.00 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	121 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	CHEMPLAST SANMAR LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007529AM24
RA File Number	04AX04000830 AM24
Licence No and Date	0411006605/21/12/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Chemical reaction of the product indicating name and molecular weight of the reactants and products and stage wise yield. 2. The end use of the product and the value of by-product formed during the process.	

Case No.	122 / NC/3/MEET/Mar/202324/25													
Case Status	Case Approved													
Party Name	HARMAN FINOCHEM LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024													
HQ File Number	HQRNORM APPLY 00007547AM24													
RA File Number	03AX04004274 AM24													
Licence No and Date	0311029606/22/12/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Sacubitril+Calcium (Sacubitril Calcium)</td><td>1 kg.</td><td>1</td><td>2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPPA)</td><td>1.237 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPPA)	1.237 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPPA)	1.237 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	123 / NC/3/MEET/Mar/202324/25			
Case Status	Case Approved			
Party Name	HARMAN FINOCHEM LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024			
HQ File Number	HQRNORM APPLY 00007550AM24			

RA File Number	03AX04004273 AM24			
Licence No and Date	0311029607/22/12/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPPA)	1.237 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	124 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007557AM24
RA File Number	08AX04001743 AM24
Licence No and Date	0811010331/22/12/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	125 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007595AM24
RA File Number	03AX04004322 AM24
Licence No and Date	0311029676/27/12/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Propafenone HCL ER Capsules USP 225 MG 60' s us (Ris((13,998 Bottles X 60 Capsules Per Bottles = 8,39,880 Capsules)(Total Weight of Export Product = 188.97 Kgs) (Net Content weight of Import Product = 207.87 kgs))	839880 Numbers	1	Propafenone Hydrochloride	192.75 kg
Propafenone HCL ER Capsules USP 325 MG 60' s us (Ris((40,838 Bottles X 60 Capsules Per Bottles = 24,50,280 Capsules) (Total Weight of Export Product = 796.34 Kgs) (Net Content weight of Import Product = 875.98 kgs))	2450280 Numbers	2	Propafenone Hydrochloride	812.27 kg

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

Case No.	126 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007599AM24
RA File Number	03AX04004373 AM24
Licence No and Date	0311029682/27/12/2023
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along relevant documents from the firm.	

Case No.	127 / NC/3/MEET/Mar/202324/25
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024

HQ File Number	HQRNORM APPLY 00007600AM24
RA File Number	03AX04004374 AM24
Licence No and Date	0311029686/27/12/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	128 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007607AM24
RA File Number	09AX04000784 AM24
Licence No and Date	0911006446/28/12/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Sep/202324/14 dated 27/09/2023** against advance authorization **No.0911005617 dated 10.08.2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
GCLE (7-PHENYLACETAMIDEO- 3-CHLOROMETHYL CEPHALOSPORANIC ACID PARA METHOXY BENZYL ESTER) (WHITE CRYSTALLINE POWDER)	1 kg	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg
		2	ACETONE	1.971 kg
		3	METHYLENE CHLORIDE MDC	3.29 kg
		4	2 MERCAPTO BENZO THIAZOLE MBT	0.511 kg
		5	METHANOL	1.971 kg

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

Case No.	129 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007629AM24
RA File Number	03AX04004329 AM24
Licence No and Date	0311029758/29/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Fluorouracil INJ BP 500 MG/10ML	68230 Vials	1	Fluorouracil IP BP	36.708 kg
Fluorouracil INJ BP 1000 MG/20 ML	69650 Vials	2	Fluorouracil IP BP	73.133 kg

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

Case No.	130 / NC/3/MEET/Mar/202324/25
Case Status	Case Approved
Party Name	MSN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 25 and 11/03/2024
HQ File Number	HQRNORM APPLY 00007630AM24
RA File Number	09AX04000831 AM24
Licence No and Date	0911006451/29/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Aliskiren Hemifumarate (API)	1 kg	1	Tert-Butyl(1S,3S)-1-((2S,4S)-4-isopropyl-5-oxotetrahydro furan-2-yl)-3-(4-methoxy-3-(3-methoxypropoxy)benzyl)-4-methylpentylcarbamate	1.18 kg
RA concerned may take further necessary action as per above decision of NC.				