



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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Mar/202425/18

DATED: 17/03/2025

Minutes of the Norms Committee 3 Meeting No. NC/3/MEET/Mar/202425/18 dated 17/03/2025, under the Chairmanship of Shri Rakesh Kumar, Addl. DGFT for considering the cases/issues under Duty Exemption Scheme (Chapter-4) of the Foreign Trade Policy, 2023 pertaining to Chemical and Allied products falling under Chapter 29 and 30.

2. The following members were present in the meeting:-

S.No.	Name and Designation	Department
1	Shri Dinesh Narain Mathur, Technical Expert	Consultant (Pharma)
2	Shri Shaish Kumar, Technical Expert	Consultant (Chemical)
3	Shri Nand Lal, Technical Expert	Consultant (Chemical)
In attendance:		
1	Shri Raman Kumar, Deputy DGFT	DGFT (HQ)
2	Shri Uttam Dey Sarkar, ASO	DGFT (HQ)

3. The Norms Committee has taken decisions only with respect to technical aspect/ wastage norms While redeeming the application, RAs should check that the applicant has fulfilled all requirements as prescribed in policy/procedure, including those in notifications, public notices and policy circulars issued from time to time or any other provisions under FTP/HBP for issuance of Advance Authorization and regularisation of the case

4. RAs shall ensure compliance with SION, General Notes and Chapter Notes wherever applicable.

5. RAs shall also ensure that authorization is issued or redeemed based on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less. In this regard, full compliance with the provisions of Para 4.12 of FTP, Para 4.16, Para 4.21, and Para 4.51 of HBP shall be made.

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Mar/202425/18													
Case Status	Case Approved													
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025													
HQ File Number	HQRNORM APPLY 00000291AM25													
RA File Number	NA													
Licence No and Date	NA													
Norms Committee Decision:														
Decision: The Committee considered the request of firm for fixation of ad-hoc norms to enable them to obtain Advance Authorization from concerned RA and it was decided to fix ad-hoc norms as per details given below or as applied by the firm, whichever is less:- (para 4.06)														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Terpineol</td><td>1 kg.</td><td>1</td><td>Gum Terpentine Oil containing Alpha Pinene 82.5%</td><td>1.95 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Terpineol	1 kg.	1	Gum Terpentine Oil containing Alpha Pinene 82.5%	1.95 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Terpineol	1 kg.	1	Gum Terpentine Oil containing Alpha Pinene 82.5%	1.95 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	2 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	ADSILO ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002270AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The Committee considered the case as per agenda, and it has been observed that the firm has added the weight of shell in the potency of Soft Gelatin Capsule, which is not certified by Drug Manufacturing License and not in convention. Further, other issues related to the content of the shell are to be provided. Therefore, it was decided to contact the firm to attend a personal hearing before the Norms Committee to explain its case, along with purchase orders and other relevant details.	

Case No.	3 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	TROIKAA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002512AM25
RA File Number	NA
Licence No and Date	NA

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms to enable them to obtain Advance Authorization from concerned RA and it was decided to fix ad-hoc norms as per details given below or as applied by the firm, whichever is less:- (para 4.06)

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Drug Formulations Injections (ampoules / vials above 10 ML) (Propofol Injection) (20 ml. Injection)	1 Number	1	Propofol	210.00 mg.
		2	E 80 (Egg Lecithin)	240.00 mg.
		3	Sodium Oleate B	6.00 mg.
		4	Purified Soyabean Oil 700	2000.00 mg.
		5	Rubber stopper	Relevant, as per Packing Policy and General Notes.

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

Case No.	4 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VINDHYA ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002820AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	

The Committee considered the request of firm for fixation of ad-hoc norms to enable them to obtain Advance Authorization from concerned RA and it was decided to fix ad-hoc norms as per details given below or as applied by the firm, whichever is less:- (para 4.06)

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
(1S,4R)-4-(2-AMINO-6-CHLORO-9H-PURIN-YL)-2-CYCLOPENTANE-1-METHANOL(AFC-2FB) (or) AbacavirSulfate (ABC) I (SA)	1 kg.	1	2-AZABICYCLO (2.2.1)HEPT-5-EN-3-ONE (VINCELACTAM)	1.75 kg.
		2	N-(2-AMINO-4, 6-DICHLORO-5-PYRIMIDINYL) FORMAMIDE	1.07 kg.
		3	SODIUM BOROHYDRIDE POWDER	0.44 kg.
		4	D(-) TARTARIC ACID	0.088 kg.
		5	L + TARTARIC ACID	1.54 kg.
		6	ISO PROPYL ALCOHOL	2.24 kg.
		7	TRIETHYL ORTHOFORMATE (TEOF)	1.16 kg.

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

Case No.	5 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	ANUPAM RASAYAN INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	018205000924AM10
RA File Number	522404000031 AM10
Licence No and Date	5210029505/27/01/2010
Norms Committee Decision:	

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

- I. Complete technical details as per Annexure to Appendix 4E for chemical products.
- II. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.
- III. Material balance for entire process.

Case No.	6 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	VIJAYASRI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	018305000961AM12
RA File Number	092404000478 AM12
Licence No and Date	0910051240/13/02/2012

Norms Committee Decision:

The Committee considered the case as per agenda and it has been observed that the application of the firm was transferred by NC-4 and no such attachment of the application is available on the portal. Therefore, it was decided to call for following information/documents from the firm:-

- I. Complete technical details as per Annexure to Appendix 4E for chemical products.
- II. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.
- III. Material balance for entire process.

It is also decided to send a letter to RA to upload copy of licence, applications and other details on the portal.

Case No.	7 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00009259AM24
RA File Number	039504000262 AM13
Licence No and Date	0310705888/22/08/2012

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.	Import Items	Qty.
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		No.		allowed.
4-AMINO-2-CHLORO-ALPHA (4-CHLOROPHENYL)	1 kg.	1	4-CHLOROBENZYL CYANIDE 99%	0.78 kg.
5-METHYL BENZENE ACETO NITRILE		2	4-CHLORO-2 NITRO TOLUENE 99%	0.68 kg.

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

Case No.	8 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	SWEMED DIAGNOSTICS
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	018305000077AM15
RA File Number	072404000426 AM14
Licence No and Date	0710102252/20/02/2014
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed that the application of the firm was transferred by NC-4 and no such attachment of the application is available on Portal. Therefore, it was decided that the firm may be advised to submit complete application alongwith relevant documents to enable to consider the request of the firm. It is also decided to send a letter to RA to upload copy of licence, applications and other details on the portal.	

Case No.	9 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	NECTAR LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001482AM25
RA File Number	222404000083 AM14
Licence No and Date	2210015019/15/07/2014
Norms Committee Decision: The representative of the firm attended personal hearing through Video Conference and explain their case. The Committee heard the explanation of the firm and after due deliberation it was directed to firm to furnish the following information/documents for further consideration:-	

1. Copy of Certificate of Analysis (CoA) of export item for the relevant period of 2014-2015.

Case No.	10 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	UNIJULES LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	018305000700AM15
RA File Number	039504000413 AM15
Licence No and Date	0310787952/12/08/2014
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. Complete technical details as per Annexure to Appendix 4E. II. Copy of Drug Manufacturing License (DML) showing approved composition of each export item. III. Master-Batch Formula for each export item showing net content of each input.	

Case No.	11 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001409AM25
RA File Number	039404000525 AM17
Licence No and Date	0310807975/22/09/2016
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Percentage yield of reaction on molar basis. 2. If yield is less than 80% justification for the same. 3. Quantity and value of by-product obtained. 4. Certificate of Analysis (CoA) of export item with percentage purity and impurity profile. 5. Production/Consumption data for licensing period duly certified by authorized Auditor of the firm.	

Case No.	12 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001645AM25

RA File Number	092404000590 AM17			
Licence No and Date	0910065113/31/05/2017			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-PHENYL ACETAMIDEO-3-CHLOROMETHYL-CEPHALOSPORANIC ACID PARA-METHOXY BENZYL ESTER)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg.
		2	ACETONE	1.971 kg.
		3	ISOPROPYL ALCOHOL	0.66 kg.
		4	METHYLENE CHLORIDE(MDC)	3.29 kg.
		5	2 MERCAPTO BENZO THIAZOLE(MBT)	0.511 kg.
		6	METHANOL	1.971 kg.

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

Case No.	13 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002136AM25
RA File Number	052304000266 AM18
Licence No and Date	0510404285/13/10/2017
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
IOPAMIDOL (612.34mg/ml) Injection. 300mgI/ml. 30ml Vial. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	1 Number	1	IOPAMIDOL USP. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	19.289 gm.
IOPAMIDOL (612.34mg/ml) Injection. 300mgI/ml. 50ml Vial. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	1 Number	2	IOPAMIDOL USP. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	32.148 gm.
IOPAMIDOL (612.34mg/ml) Injection. 300mgI/ml. 100ml Vial. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	1 Number	3	IOPAMIDOL USP. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	64.296 gm.
IOPAMIDOL (755.22mg/ml) Injection. 370mgI/ml. 30ml Vial. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	1 Number	4	IOPAMIDOL USP. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	23.789 gm.
IOPAMIDOL (755.22mg/ml) Injection. 370mgI/ml. 50ml Vial. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	1 Number	5	IOPAMIDOL USP. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	39.65 gm.
IOPAMIDOL (755.22mg/ml) Injection. 370mgI/ml. 100ml Vial. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	1 Number	6	IOPAMIDOL USP. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	79.30 gm.

IOPAMIDOL (755.22mg/ml) Injection. 370mgI/ml. 200ml Vial. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	1 Number	7	IOPAMIDOL USP. IMPORT & EXPORT TO BE GOVERNED AS PER P/C 9 DATED 30.06.2003	158.60 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	14 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002128AM25
RA File Number	039404000726 AM18
Licence No and Date	0310817755/13/12/2017

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.4/82-ALC4/2018 dated 19/06/2018 against advance authorization No.0310817755 dated 13/12/2017 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ipratropium Pressurised Inhalation 20mcg / Ipravent 20mcg Inhaler (200MD) (Ipramar 20mcg Inhaler / INFLUMIX 20 MCG (200MD) with 63mcl Aerosol Valve, 19ml Plasma Coated Aluminium Can with 0.48mm Actuator HFA 227 Gas 21.30 gms)	1 kg.	1	Ipratropium Bromide	4.00 mg.
		4	63mcl AEROSOL VALVES	Relevant, as per Packing Policy and General Notes.
		7	19ml Plasma Coated ALUMINIUM CAN	
		10	0.48 mm OD ACTUATORS WITH DUST COVERS / CAPS	

		13	Heptafluoropropane P227 Gas (HFA-227)	21.12 mg.
Ipratropium Pressurised Inhalation 40mcg / Ipravent 40mcg Inhaler (200MD) Ipramar 40mcg Inhaler(with 63mcl Aerosol Valve, 19ml Plasma Coated Aluminium Can with 0.48mm Actuator HFA 227 Gas 21.25 gms)	1 kg.	2	Ipratropium Bromide	8.00 mg.
		5	63mcl AEROSOL VALVES	Relevant, as per Packing Policy and General Notes.
		8	19ml Plasma Coated ALUMINIUM CAN	
		11	0.48 mm OD ACTUATORS WITH DUST COVERS / CAPS	
		14	Heptafluoropropane P227 Gas	21.12 mg.
Ipratropium Bromide 20mcg and Salbutamol Sulphate 100mcg Inhaler (200MD) DUOLIN INHALER (200MD) (with 63mcl Aerosol Valve, 19ml Plasma coated Aluminium Can with 0.58mm Actuator HFA 227 Gas 21.10 gms)	1 kg.	3	Ipratropium Bromide	4.00 mg.
		6	63mcl AEROSOL VALVES	Relevant, as per Packing Policy and General Notes.
		9	19ml Plasma Coated ALUMINIUM CAN	
		12	0.58 mm OD ACTUATORS WITH DUST COVERS / CAPS	
		15	Heptafluoropropane P227 Gas	21.12 mg.

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

Case No.	15 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001412AM25
RA File Number	039404000762 AM18
Licence No and Date	0310818348/09/01/2018
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. Percentage yield of reaction on molar basis. II. If yield is less than 80% justification for the same. III. Quantity and value of by-product obtained. IV. Certificate of Analysis (CoA) of export item with percentage purity and impurity profile. V. Production/Consumption data for licensing period duly certified by authorized Auditor of the firm.	

Case No.	16 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001639AM25
RA File Number	092404000511 AM18
Licence No and Date	0910066144/12/04/2018

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-PHENYL ACETAMIDEO-3-CHLOROMETHYL-CEPHALOSPORANIC ACID PARA-METHOXY BENZYL ESTER)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg.
		2	ACETONE	1.971 kg.
		3	ISOPROPYL ALCOHOL	0.66 kg.
		4	METHYLENE CHLORIDE(MDC)	3.29 kg.

		5	2 MERCAPTO BENZO THIAZOLE(MBT)	0.511 kg.
		6	METHANOL	1.971 kg.

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

Case No.	17 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001641AM25
RA File Number	092404000608 AM18
Licence No and Date	0910066145/12/04/2018

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-PHENYL ACETAMIDEO-3-CHLOROMETHYL-CEPHALOSPORANIC ACID PARAMETHOXY BENZYL ESTER)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg.
		2	ACETONE	1.971 kg.
		3	ISOPROPYL ALCOHOL	0.66 kg.
		4	METHYLENE CHLORIDE(MDC)	3.29 kg.
		5	2 -MERCAPTO BENZO THIAZOLE (MBT)	0.511 kg.
		6	METHANOL	1.971 kg.

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

Case No.	18 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001640AM25
RA File Number	092404000649 AM18
Licence No and Date	0910066322/11/06/2018

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-PHENYL ACETAMIDEO-3-CHLOROMETHYL-CEPHALOSPORANIC ACID PARA-METHOXY BENZYL ESTER)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg.
		2	ACETONE	1.971 kg.
		3	ISOPROPYL ALCOHOL	0.66 kg.
		4	METHYLENE CHLORIDE(MDC)	3.29 kg.
		5	2 -MERCAPTO BENZO THIAZOLE (MBT)	0.511 kg.
		6	METHANOL	1.971 kg.

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

Case No.	19 / NC/3/MEET/Mar/202425/18
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Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001643AM25
RA File Number	092404000623 AM18
Licence No and Date	0910066323/11/06/2018

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-PHENYL ACETAMIDEO-3-CHLOROMETHYL-CEPHALOSPORANIC ACID PARAMETHOXY BENZYL ESTER)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg.
		2	ACETONE	1.971 kg.
		3	ISOPROPYL ALCOHOL	0.66 kg.
		4	METHYLENE CHLORIDE(MDC)	3.29 kg.
		5	2 -MERCAPTO BENZO THIAZOLE (MBT)	0.511 kg.
		6	METHANOL	1.971 kg.

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

Case No.	20 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001642AM25
RA File Number	092404000137 AM19
Licence No and Date	0910066398/28/06/2018

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-PHENYL ACETAMIDEO-3-CHLOROMETHYL-CEPHALOSPORANIC ACID PARAMETHOXY BENZYL ESTER)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg.
		2	ACETONE	1.971 kg.
		3	ISOPROPYL ALCOHOL	0.66 kg.
		4	METHYLENE CHLORIDE(MDC)	3.29 kg.
		5	2 -MERCAPTO BENZO THIAZOLE (MBT)	0.511 kg.
		6	METHANOL	1.971 kg.

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

Case No.	21 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001644AM25
RA File Number	092404000065 AM19
Licence No and Date	0910066425/06/07/2018

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GCLE(7-PHENYL ACETAMIDEO-3-CHLOROMETHYL-CEPHALOSPORANIC ACID PARA-METHOXY BENZYL ESTER)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg.
		2	ACETONE	1.971 kg.
		3	ISOPROPYL ALCOHOL	0.66 kg.
		4	METHYLENE CHLORIDE(MDC)	3.29 kg.
		5	2 -MERCAPTO BENZO THIAZOLE (MBT)	0.511 kg.
		6	METHANOL	1.971 kg.

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

Case No.	22 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001454AM25
RA File Number	039404000390 AM19
Licence No and Date	0310822723/31/07/2018
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- - Percentage yield of reaction on molar basis. - If yield is less than 80% justification for the same. - Quantity and value of by-product obtained. - Certificate of Analysis (CoA) of export item with percentage purity and impurity profile. - Why export product No. 1 is call as natural when it is made synthetically.	

VI. Production/Consumption data for licensing period duly certified by authorized Auditor of the firm.

Case No.	23 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	SHUBHLAXMI INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002134AM25
RA File Number	082404000267 AM19
Licence No and Date	0810144119/20/12/2018
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. Complete and balanced chemical reactions, showing molecular weight and percentage yield on molar basis. II. Complete technical details as per Annexure to Appendix 4E for chemical products.	

Case No.	24 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001411AM25
RA File Number	039404000052 AM20
Licence No and Date	0310828561/24/04/2019
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. Percentage yield of reaction on molar basis. II. If yield is less than 80% justification for the same. III. Quantity and value of by-product obtained. IV. Certificate of Analysis (CoA) of export item with percentage purity and impurity profile. V. Complete technical details as per Annexure to Appendix-4E for chemical products. VI. Production/Consumption data for licensing period duly certified by authorized Auditor of the firm.	

Case No.	25 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025

and Date	
HQ File Number	018205000499AM20
RA File Number	039404000373 AM20
Licence No and Date	0310830887/07/08/2019
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. Exact chemical name of import and export items. II. Certificate of Analysis (CoA) of import from foreign supplier indicating weight wise percentage composition III. Certificate of Analysis (CoA) of export item. IV. Complete technical details as per Annexure to Appendix-4E for chemical products. V. Production/Consumption data for licensing period duly certified by authorized Auditor of the firm.	

Case No.	26 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001456AM25
RA File Number	039404000462 AM20
Licence No and Date	0310831524/13/09/2019
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. Percentage yield of reaction on molar basis. II. If yield is less than 80% justification for the same. III. Quantity and value of by-product obtained. IV. Certificate of Analysis (CoA) of export item with percentage purity and impurity profile. V. Why export product No. 1 is call as natural when it is made synthetically. VI. Complete technical details as per Annexure to Appendix-4E for chemical products. VII. Production/Consumption data for licensing period duly certified by authorized Auditor of the firm.	

Case No.	27 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002103AM25
RA File Number	039404000526 AM20

Licence No and Date	0310832396/23/10/2019			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ashoxy 5% (100ML VIAL)(Oxytetracycline Hydrochloride Injection 50mg)	1 Number	1	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 10% (100 ML VIAL)(Oxytetracycline Injection 100mg)	1 Number	2	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 20% LA (100 ML VIAL)(Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg)	1 Number	3	PROPYLENE GLYCOL	18.00 gm/Vial
Ashiver 1% (100 ML VIAL)(Ivermectin 10 Mg Injection)	1 Number	4	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1% (50 ML VIAL)(Ivermectin 10 Mg Injection)	1 Number	5	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver Forte (100 ML VIAL)(Ivermectin 10mg and Clorsulon 100mg Injection)	1 Number	6	PROPYLENE GLYCOL	101.92 gm/Vial
Ashienro 10% (100 ML VIAL)(Enrofloxacin Injection 100mg)	1 Number	7	PROPYLENE GLYCOL	10.40 gm/Vial
Ashityl 20% (100 ML VIAL)(Tylosin Tartrate injection eq to Tylosin 200mg)	1 Number	8	PROPYLENE GLYCOL	20.80 gm/Vial

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

Case No.	28 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00009300AM24
RA File Number	052404000670 AM20
Licence No and Date	0510413367/17/01/2020

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Terpineol	1 kg.	1	Gum Terpine Oil containing Alpha Pinene 82.5%	1.95 kg.

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

Case No.	29 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00009301AM24
RA File Number	052404000729 AM20
Licence No and Date	0510413656/19/02/2020

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Terpineol	1 kg.	1	Gum Terpine Oil containing Alpha Pinene 82.5%	1.95 kg.

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

Case No.	30 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00009299AM24
RA File Number	052404000071 AM21
Licence No and Date	0510414288/29/05/2020

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Terpineol	1 kg.	1	Gum Terpentine Oil containing Alpha Pinene 82.5%	1.95 kg.

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

Case No.	31 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	SAVLA CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002129AM25
RA File Number	039504000192 AM21
Licence No and Date	0310837078/08/07/2020

Norms Committee Decision:

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

1. Certificate of Analysis (CoA) of import item indicating percentage purity.
2. Copies of the Bill of Entry indicating percentage purity.

Case No.	32 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001452AM25
RA File Number	039404000218 AM21
Licence No and Date	0310837120/09/07/2020
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. Percentage yield of reaction on molar basis. II. If yield is less than 80% justification for the same. III. Quantity and value of by-product obtained. IV. Certificate of Analysis (CoA) of export item with percentage purity and impurity profile. V. Why export product No. 1 is call as natural when it is made synthetically. VI. Complete technical details as per Annexure to Appendix-4E for chemical products. VII. Production/Consumption data for licensing period duly certified by authorized Auditor of the firm.	

Case No.	33 / NC/3/MEET/Mar/202425/18													
Case Status	Case Approved													
Party Name	GLOBAL CALCIUM PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025													
HQ File Number	HQRNORM REVIW00001216AM25													
RA File Number	072404000145 AM21													
Licence No and Date	0710116940/28/08/2020													
Norms Committee Decision:														
Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Oct/202223/11 dated 31/10/2022 against advance authorization No.0711002507 dated 02/12/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>ZINC GLUCONATE POWDER</td><td>-1 kg.</td><td>1</td><td>ZINC GLUCONATE - GRANULAR</td><td>1.005 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ZINC GLUCONATE POWDER	-1 kg.	1	ZINC GLUCONATE - GRANULAR	1.005 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
ZINC GLUCONATE POWDER	-1 kg.	1	ZINC GLUCONATE - GRANULAR	1.005 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	34 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002102AM25
RA File Number	039404000571 AM21
Licence No and Date	0310839148/27/10/2020

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to fix ad-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.
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial	1 Number	1	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial	1 Number	2	PROPYLENE GLYCOL	39.52 gm/vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial	1 Number	3	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 50ml vial	1 Number	4	PROPYLENE GLYCOL	35.256 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 100ml vial	1 Number	5	PROPYLENE GLYCOL	18.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 100ml vial	1 Number	6	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 50ml vial	1 Number	7	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver Forte (Ivermectin 10mg	1 Number	8	PROPYLENE GLYCOL	101.92 gm/Vial

and Clorsulon 100mg Injection) 100ml vial				
Ashienro 10% (Enrofloxacin Injection 100mg) 100ml vial	1 Number	9	PROPYLENE GLYCOL	10.40 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	10	PROPYLENE GLYCOL	20.80 gm/Vial

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

Case No.	35 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002101AM25
RA File Number	03AA04011100 AM22
Licence No and Date	0311003600/06/05/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ashoxy 5PCT (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial
Ashoxy 5PCT (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 5PCT (Oxytetracycline Hydrochloride Injection 50mg) 250ml vial	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial
Ashoxy 5PCT (Oxytetracycline Hydrochloride Injection 50mg) 500ml	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial

vial				
Ashoxy 10PCT (Oxytetracycline Injection 100mg) 50ml vial	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial
Ashoxy 10PCT (Oxytetracycline Injection 100mg) 100ml vial	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 10PCT (Oxytetracycline Injection 100mg) 250ml vial	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial
PAN Ashoxy 3PCT (Oxytetracycline Injection 30mg) 100ml vial	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 20PCT LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 50ml vial	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial
Ashoxy 20PCT LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 100ml vial	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial
Ashoxy 20PCT LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 250ml vial	1 Number	11	PROPYLENE GLYCOL	45.00 gm/Vial
Ashiver 1PCT (Ivermectin 10 Mg Injection) 50ml vial((Ivermectin 10 Mg Injection) 50ml vial	1 Number	12	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver 1PCT (Ivermectin 10 Mg Injection) 100ml vial	1 Number	13	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1PCT (Ivermectin 10 Mg Injection) 250ml vial	1 Number	14	PROPYLENE GLYCOL	260.00 gm/Vial
Ashiver 1PCT (Ivermectin 10 Mg Injection) 500ml vial	1 Number	15	PROPYLENE GLYCOL	520.00 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 100ml vial	1 Number	16	PROPYLENE GLYCOL	101.92 gm/Vial

Ashienro 10PCT (Enrofloxacin Injection 100mg) 50ml vial	1 Number	17	PROPYLENE GLYCOL	5.20 gm/Vial
Ashienro 10PCT (Enrofloxacin Injection 100mg) 100ml vial	1 Number	18	PROPYLENE GLYCOL	10.40 gm/Vial
Ashienro 10pct (Enrofloxacin Injection 100mg) 250ml vial	1 Number	19	PROPYLENE GLYCOL	26.00gm/Vial
Ashityl 20pct (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	20	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 5PCT (Tylosin Tartrate injection eq to Tylosin 50mg) 50ml vial	1 Number	21	PROPYLENE GLYCOL	10.40 gm/Vial

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

Case No.	36 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00003011AM25
RA File Number	03AA04065031 AM22
Licence No and Date	0311006216/17/08/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril/ Valsartan	500 kg.	1	2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid	279.6 kg.
		2	L-Valine	170.0 kg.

		3	4-Bromomethyl-2-Cyanobiphenyl	220.0 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	37 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002096AM25
RA File Number	03AA040112749 AM22
Licence No and Date	0311008637/17/11/2021

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.
TYLOSIN TARTRATE POWDER 100PCT-100GMSACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100PCT)	1 Number	1	TYLOSIN TARTRATE	101 gm.
TYLOSIN TARTRATE POWDER 100PCT-500GMSACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100PCT)	1 Number	2	TYLOSIN TARTRATE	505 gm.
TYLOSIN TARTRATE POWDER 100PCT-1KG JAR (EACHGRAM CONTAINS TYLOSIN TARTRATE 100PCT)	1 Nimner	3	TYLOSIN TARTRATE	1010 gm.
TYLOSIN TARTRATE POWDER 99PCT -100GMSACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 99PCT)	1 Number	4	TYLOSIN TARTRATE	100 gm.

TYLOSIN TARTRATE POWDER 99PCT -500GMSACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 99PCT)	1 Number	5	TYLOSIN TARTRATE	500 gm.
TYLOSIN TARTRATE POWDER 99PCT -1KG JAR (EACHGRAM CONTAINS TYLOSIN TARTRATE 99PCT)	1 Number	6	TYLOSIN TARTRATE	1000 gm.
TYLOSIN TARTRATE POWDER 20PCT-5GM (EACHGRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20PCT)	1 Number	7	TYLOSIN TARTRATE	1756. gm.
TYLOSIN TARTRATE POWDER 20PCT -100GM (EACHGRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20PCT)	1 Number	8	TYLOSIN TARTRATE	23.513 gm.
TYLOSIN TARTRATE POWDER 20PCT -500GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20PCT)	1 Number	9	TYLOSIN TARTRATE	117.564 gm.
TYLOSIN TARTRATE POWDER 20PCT -1KG JAR (EACHGRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20PCT)	1 Number	10	TYLOSIN TARTRATE	235.128 gm.
TYLOSIN BOLUS 200MG(TYLOSIN BOLUS 200MG (EACH BOLUS CONTAINS TYLOSIN 200MG)	1 Number	11	TYLOSIN TARTRATE	204.00 gm.
TYLOSIN INJECTION 5PCT-30 ML(TYLOSIN INJECTION 5PCT-30 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG)	1 Number	12	TYLOSIN TARTRATE	1.833 gm.
TYLOSIN INJECTION 5PCT-50 ML (EACH ML CONTAINS TYLOSIN	1 Number	13	TYLOSIN TARTRATE	3.056 gm.

TARTRATE EQ. TO TYLOSIN BASE 50MG)				
TYLOSIN INJECTION 5PCT-100 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG)	1 Number	14	TYLOSIN TARTRATE	6.111 gm.
TYLOSIN TARTRATE INJECTION 20PCT-30 ML (EACH MLCONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	15	TYLOSIN TARTRATE	7.333 gm.
TYLOSIN TARTRATE INJECTION 20PCT-50 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	16	TYLOSIN TARTRATE	12.222 gm.
TYLOSIN TARTRATE INJECTION 20PCT-100 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	17	TYLOSIN TARTRATE	24.444 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	38 / NC/3/MEET/Mar/202425/18			
Case Status	Case Approved			
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025			
HQ File Number	HQRNORM REVIW00002091AM25			
RA File Number	03AA040123869 AM22			
Licence No and Date	0311009212/06/12/2021			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 250ml vial	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 500ml vial	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 50ml vial	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 250ml vial	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial
PAN Ashoxy 3% (Oxytetracycline Injection 30mg) 100ml vial	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 50ml vial	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 100ml vial	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 250ml vial	1 Number	11	PROPYLENE GLYCOL	45.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 50ml vial	1 Number	12	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection)	1 Number	13	PROPYLENE GLYCOL	52.00 gm./Vial

50ml vial				
Ashiver 1% (Ivermectin 10 Mg Injection) 100ml vial	1 Number	14	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 250ml vial	1 Number	15	PROPYLENE GLYCOL	260.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 500ml vial	1 Number	16	PROPYLENE GLYCOL	520.00 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon100mgInjection) 100ml vial	1 Number	17	PROPYLENE GLYCOL	101.92 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon100mgInjection) 100ml vial	1 Number	18	PROPYLENE GLYCOL	101.92 gm/Vial
Ashienro 10 % (Enrofloxacin Injection 100mg) 50ml vial	1 Number	19	PROPYLENE GLYCOL	5.20 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 100ml vial	1 Number	20	PROPYLENE GLYCOL	10.40 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 250ml vial	1 Number	21	PROPYLENE GLYCOL	26.00 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin200mg) 100ml vial	1 Number	22	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 5% (Tylosin Tartrate injection eq to Tylosin50mg)50ml vial	1 Number	23	PROPYLENE GLYCOL	10.40 gm/Vial
RA concerned may take further necessary action as per above decision of NC.				

Case No.	39 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002222AM25
RA File Number	09AX04000389 AM22
Licence No and Date	0911002926/29/04/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
LiHMDS 1.0M IN TETRAHYDROFURAN (CLEAR YELLOW TO BROWN COLOR LIQUID)	1 Litre	1	LITHIUM METAL 98 % MIN	0.01 kg
		2	HEXAMETHYL DISILAZANE	0.2367 kg.
		3	TETRAHYDROFURAN	0.712 kg
		4	ISOPRENE	0.0508 kg

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

Case No.	40 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002223AM25
RA File Number	09AX04000388 AM22
Licence No and Date	0911002925/29/04/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
LiHMDS 1.0M IN TETRAHYDROFURAN (CLEAR YELLOW TO BROWN COLOR LIQUID)	1 Litre	1	LITHIUM METAL 98 % MIN	0.01 kg
		2	HEXAMETHYL DISILAZANE	0.2367 kg.
		3	TETRAHYDROFURAN	0.712 kg
		4	ISOPRENE	0.0508 kg

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

Case No.	41 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002226AM25
RA File Number	09AX04000372 AM22
Licence No and Date	0911002924/29/04/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
LiHMDS 1.0M IN TETRAHYDROFURAN (CLEAR YELLOW TO BROWN COLOR LIQUID)	1 Litre	1	LITHIUM METAL 98 % MIN	0.01 kg
		2	HEXAMETHYL DISILAZANE	0.2367 kg.
		3	TETRAHYDROFURAN	0.712 kg
		4	ISOPRENE	0.0508 kg

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

Case No.	42 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001406AM25
RA File Number	03AX04000821 AM23
Licence No and Date	0311015467/13/06/2022

Norms Committee Decision:

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

- I. Percentage yield of reaction on molar basis.
- II. If yield is less than 80% justification for the same.
- III. Quantity and value of by-product obtained.
- IV. Certificate of Analysis (CoA) of export item with percentage purity and impurity profile.

- V. Why export product No. 1 is call as natural when it is made synthetically.
- VI. Complete technical details as per Annexure to Appendix-4E for chemical products.
- VII. Production/Consumption data for licensing period duly certified by authorized Auditor of the firm.

Case No.	43 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001455AM25
RA File Number	03AX04002522 AM23
Licence No and Date	0311017151/12/08/2022

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm and it has been observed by the committee that item of export appears to be perfumery compound comes under para 4.11(b) of FTP, 2023, and the said para states that “For export of perfumes, perfumery compounds and various feed ingredients containing vitamins, no authorisation shall be issued by Regional Authority under para 4.07 of HBP and applicants shall be required to apply under para 4.06 of HBP to the Norms Committee”.

Accordingly, it was decided that a clarification in this regard may be obtained from the firm as well as RA.

Case No.	44 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	ASSOCIATED DYESTUFF PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001845AM25
RA File Number	08AX04001207 AM23
Licence No and Date	0811006504/22/11/2022

Norms Committee Decision:

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

1. Chemistry starting from Acetanilide to formation of end product giving molecular weight of all the reactant and product.
2. Yield of reaction and reason for low yield, if any.
3. End use of Export product

Case No.	45 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved

Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00006136AM24
RA File Number	52AX04001711 AM23
Licence No and Date	5211003710/07/12/2022

Norms Committee Decision:

The representative of the firm attended personal hearing through Video Conference and explains their case. The Committee heard the explanation of the firm and after due deliberation it was decided to fix the norms as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-{1-[(2S)-2-Aminopropyl]-1-H-Pyrazole-3-yl}-2-Chlorobenzonitrile	1 kg.	1	Triphenylphosphine	1.237 kg.
		2	Tert-Butyl((1S)-2-hydroxy-1-methylethyl)carbamate (DARO-IV)	0.826 kg.
		3	(S)-4-(1-(2-aminopropyl)-1H-pyrazol-3-yl)-2-chlorobenzonitrile (DARO-V)	0.001 kg.
		4	2-chloro-4-(1H-pyrazol-3-yl)benzonitrile (DARO-III)	0.963 kg.
		5	Diisopropyl azodicarboxylate (DIAD)	1.034 kg.

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

Case No.	46 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VINS BIOPRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00000068AM24
RA File Number	09AX04001155 AM23
Licence No and Date	0911004801/10/04/2023
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.
Tetanus Antitoxin I.H.S / B.P 1500 IU / ML Plus [overage of 150 IU in addition] in PFS / vials / Ampoule) [733333 Vials]	1,00,000 Vials	1	Tetanus Antitoxin 2500 I.U / ml	69.3 Liter

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

Case No.	47 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00003637AM25
RA File Number	09AX04000067 AM24
Licence No and Date	0911004910/28/04/2023

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.
Benzyl (1S,2R,3R,4aR,6aS,7R,8R,10aR,10bR,12aR) -3- hydrazineyl-2-hydroxy-1,6a,8,10a-tetramethyl-8- ((R)-3-methylbutan. (-2-yl)- 1, 3, 4, 6, 6a, 7, 8, 9, 10, 10a,10b,11,12,12a-tetradecahydro-2H-1,4a- (methanooxymethano) chrysene-7-carboxylate (Drug Intermediate of Ibrexafungerp Citrate))	1 kg.	1	ENFUMAFUNGIN	2.086 kg.

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

Case No.	48 / NC/3/MEET/Mar/202425/18
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Case Status	Case Approved														
Party Name	NEULAND LABORATORIES LTD.														
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025														
HQ File Number	HQRNORM REVIW00003635AM25														
RA File Number	09AX04000052 AM24														
Licence No and Date	0911004957/03/05/2023														
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:-															
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Benzyl (1S,2R,3R,4aR,6aS,7R,8R,10aR,10bR,12aR) -3-hydrazineyl-2-hydroxy-1,6a,8,10a-tetramethyl-8-((R)-3-methylbutan. (-2-yl)- 1, 3, 4, 6, 6a, 7, 8, 9, 10, 10a,10b,11,12,12a-tetradecahydro-2H-1,4a-(methanooxymethano) chrysene-7-carboxylate (Drug Intermediate of Ibrexafungerp Citrate))</td><td>1 kg.</td><td>1</td><td>ENFUMAFUNGIN</td><td>2.086 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Benzyl (1S,2R,3R,4aR,6aS,7R,8R,10aR,10bR,12aR) -3-hydrazineyl-2-hydroxy-1,6a,8,10a-tetramethyl-8-((R)-3-methylbutan. (-2-yl)- 1, 3, 4, 6, 6a, 7, 8, 9, 10, 10a,10b,11,12,12a-tetradecahydro-2H-1,4a-(methanooxymethano) chrysene-7-carboxylate (Drug Intermediate of Ibrexafungerp Citrate))	1 kg.	1	ENFUMAFUNGIN	2.086 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.											
Benzyl (1S,2R,3R,4aR,6aS,7R,8R,10aR,10bR,12aR) -3-hydrazineyl-2-hydroxy-1,6a,8,10a-tetramethyl-8-((R)-3-methylbutan. (-2-yl)- 1, 3, 4, 6, 6a, 7, 8, 9, 10, 10a,10b,11,12,12a-tetradecahydro-2H-1,4a-(methanooxymethano) chrysene-7-carboxylate (Drug Intermediate of Ibrexafungerp Citrate))	1 kg.	1	ENFUMAFUNGIN	2.086 kg.											
RA concerned may take further necessary action as per above decision of NC.															

Case No.	49 / NC/3/MEET/Mar/202425/18			
Case Status	Case Approved			
Party Name	NEULAND LABORATORIES LTD.			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025			
HQ File Number	HQRNORM REVIW00003638AM25			
RA File Number	09AX04000149 AM24			
Licence No and Date	0911005088/22/05/2023			
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.
Benzyl (1S,2R,3R,4aR,6aS,7R,8R,10aR,10bR,12aR) -3-	1 kg.	1	ENFUMAFUNGIN	2.086 kg.

hydrazineyl-2-hydroxy-1,6a,8,10a-tetramethyl-8-((R)-3-methylbutan. (-2-yl)- 1, 3, 4, 6, 6a, 7, 8, 9, 10, 10a,10b,11,12,12a-tetradecahydro-2H-1,4a-(methanooxymethano) chrysene-7-carboxylate (Drug Intermediate of Ibrexafungerp Citrate))				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	50 / NC/3/MEET/Mar/202425/18										
Case Status	Case Approved										
Party Name	NEULAND LABORATORIES LTD.										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025										
HQ File Number	HQRNORM REVIW00003640AM25										
RA File Number	09AX04000170 AM24										
Licence No and Date	0911005122/26/05/2023										
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:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Benzyl (1S,2R,3R,4aR,6aS,7R,8R,10aR,10bR,12aR) -3-hydrazineyl-2-hydroxy-1,6a,8,10a-tetramethyl-8-((R)-3-methylbutan. (-2-yl)- 1, 3, 4, 6, 6a, 7, 8, 9, 10, 10a,10b,11,12,12a-tetradecahydro-2H-1,4a-(methanooxymethano) chrysene-7-carboxylate (Drug Intermediate of Ibrexafungerp Citrate))</td><td>1 kg.</td><td>1</td><td>ENFUMAFUNGIN</td><td>2.086 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Benzyl (1S,2R,3R,4aR,6aS,7R,8R,10aR,10bR,12aR) -3-hydrazineyl-2-hydroxy-1,6a,8,10a-tetramethyl-8-((R)-3-methylbutan. (-2-yl)- 1, 3, 4, 6, 6a, 7, 8, 9, 10, 10a,10b,11,12,12a-tetradecahydro-2H-1,4a-(methanooxymethano) chrysene-7-carboxylate (Drug Intermediate of Ibrexafungerp Citrate))	1 kg.	1	ENFUMAFUNGIN	2.086 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Benzyl (1S,2R,3R,4aR,6aS,7R,8R,10aR,10bR,12aR) -3-hydrazineyl-2-hydroxy-1,6a,8,10a-tetramethyl-8-((R)-3-methylbutan. (-2-yl)- 1, 3, 4, 6, 6a, 7, 8, 9, 10, 10a,10b,11,12,12a-tetradecahydro-2H-1,4a-(methanooxymethano) chrysene-7-carboxylate (Drug Intermediate of Ibrexafungerp Citrate))	1 kg.	1	ENFUMAFUNGIN	2.086 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	51 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00001348AM24
RA File Number	08AX04000333 AM24
Licence No and Date	0811008323/06/06/2023
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.
NORELGESTROMIN AND ETHINYL ESTRADIOL TRANSDERMAL SYSTEM 150/35 MCG PER DAY((EACH 15.75 CM2 PATCH CONTAINS: NORELGESTROMIN USP 4.678 MG TO PROVIDE NORELGESTROMIN 150 MCG/DAY & ETHINYL ESTRADIOL USP 0.53 MG TO PROVIDE ETHINYL ESTRADIOL 35 MCG/DAY))	1 Patch	1	NORELGESTROMIN USP	5.8475 mg/ Patch
		2	ETHINYL ESTRADIOL USP	0.6625 mg/ Patch

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

Case No.	52 / NC/3/MEET/Mar/202425/18
Case Status	Case Rejected
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002105AM25
RA File Number	07AX04000371 AM24
Licence No and Date	0711008304/19/06/2023

Norms Committee Decision:

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

Case No.	53 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002092AM25
RA File Number	03AX04001845 AM24

Licence No and Date	0311025665/24/07/2023																																																											
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:-																																																												
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial</td><td>1 Number</td><td>1</td><td>PROPYLENE GLYCOL</td><td>39.52 gm/Vial</td></tr><tr><td>Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial</td><td>1 Number</td><td>2</td><td>PROPYLENE GLYCOL</td><td>79.04 gm/Vial</td></tr><tr><td>Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 250ml vial</td><td>1 Number</td><td>3</td><td>PROPYLENE GLYCOL</td><td>197.60 gm/Vial</td></tr><tr><td>Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 500ml vial</td><td>1 Number</td><td>4</td><td>PROPYLENE GLYCOL</td><td>395.20 gm/Vial</td></tr><tr><td>Ashoxy 10% (Oxytetracycline Injection 100mg) 50ml vial</td><td>1 Number</td><td>5</td><td>PROPYLENE GLYCOL</td><td>35.256 gm/Vial</td></tr><tr><td>Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial</td><td>1 Number</td><td>6</td><td>PROPYLENE GLYCOL</td><td>70.512 gm/Vial</td></tr><tr><td>Ashoxy 10% (Oxytetracycline Injection 100mg) 250ml vial</td><td>1 Number</td><td>7</td><td>PROPYLENE GLYCOL</td><td>176.28 gm/Vial</td></tr><tr><td>PAN Ashoxy 3% (Oxytetracycline Injection 30mg) 100ml vial</td><td>1 Number</td><td>8</td><td>PROPYLENE GLYCOL</td><td>70.512 gm/Vial</td></tr><tr><td>Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 50ml vial</td><td>1 Number</td><td>9</td><td>PROPYLENE GLYCOL</td><td>9.00 gm/Vial</td></tr><tr><td>Ashoxy 20% LA (Oxytetracycline</td><td>1 Number</td><td>10</td><td>PROPYLENE GLYCOL</td><td>18.00 gm/Vial</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial	Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial	Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 250ml vial	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial	Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 500ml vial	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial	Ashoxy 10% (Oxytetracycline Injection 100mg) 50ml vial	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial	Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial	Ashoxy 10% (Oxytetracycline Injection 100mg) 250ml vial	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial	PAN Ashoxy 3% (Oxytetracycline Injection 30mg) 100ml vial	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial	Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 50ml vial	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial	Ashoxy 20% LA (Oxytetracycline	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																																																								
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial																																																								
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial																																																								
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 250ml vial	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial																																																								
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 500ml vial	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial																																																								
Ashoxy 10% (Oxytetracycline Injection 100mg) 50ml vial	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial																																																								
Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial																																																								
Ashoxy 10% (Oxytetracycline Injection 100mg) 250ml vial	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial																																																								
PAN Ashoxy 3% (Oxytetracycline Injection 30mg) 100ml vial	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial																																																								
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 50ml vial	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial																																																								
Ashoxy 20% LA (Oxytetracycline	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial																																																								

Dihydrate Injection eqOxytetracycline 200mg) 100ml vial				
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 250ml vial	1 Number	11	PROPYLENE GLYCOL	45.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 10ml viaL	1 Number	12	PROPYLENE GLYCOL	10.40 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 50ml vial	1 Number	13	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 100ml vial	1 Number	14	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 250ml vial	1 Number	15	PROPYLENE GLYCOL	260.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 500ml vial	1 Number	16	PROPYLENE GLYCOL	520.00 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 50ml viaL	1 Number	17	PROPYLENE GLYCOL	50.96 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 100ml vial	1 Number	18	PROPYLENE GLYCOL	101.92 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 50ml vial	1 Number	19	PROPYLENE GLYCOL	5.20 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 100ml vial	1 Number	20	PROPYLENE GLYCOL	10.40 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 250ml vial	1 Number	21	PROPYLENE GLYCOL	26.00 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	22	PROPYLENE GLYCOL	20.80 gm/Vial

Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	23	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	24	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 5% (Tylosin Tartrate injection eq to Tylosin 50mg) 50ml vial	1 Number	25	PROPYLENE GLYCOL	10.40 gm/Vial
Ashital 10% (Closantel 10% Inj) 100ml vial	1 Number	26	PROPYLENE GLYCOL	55.12 gm/Vial

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

Case No.	54 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002097AM25
RA File Number	03AX04001847 AM24
Licence No and Date	0311025741/25/07/2023

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.
TYLOSIN BOLUS 200MG (EACH BOLUS CONTAINS TYLOSIN 200MG)	1 Number	1	TYLOSIN TARTRATE	204.00 gm.
TYLOSIN INJECTION 5%-50 ML (EACH ML CONTAINS TYLOSIN TARTRATEEQ. TO TYLOSIN BASE 50MG)	1 Number	2	TYLOSIN TARTRATE	3.056 gm.
TYLOSIN INJECTION 5%-100 ML	1 Number	3	TYLOSIN TARTRATE	6.111 gm.

(EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG)				
TYLOSIN TARTRATE INJECTION 20%-50 ML (EACH MLCONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	4	TYLOSIN TARTRATE	12.222 gm.
TYLOSIN TARTRATE INJECTION 20%-100 ML (EACH MLCONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	5	TYLOSIN TARTRATE	24.444 gm.
TYLOSIN TARTRATE POWDER 100%-100GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	6	TYLOSIN TARTRATE	101 gm.
TYLOSIN TARTRATE POWDER 100% -500GM SACHET(EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	7	TYLOSIN TARTRATE	505 gm.
TYLOSIN TARTRATE POWDER 100% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	8	TYLOSIN TARTRATE	1010 gm.
TYLOSIN TARTRATE POWDER 20%-5GM (EACH GRAM CONTAINSTYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	9	TYLOSIN TARTRATE	1.1756 gm.
TYLOSIN TARTRATE POWDER 20% -100GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	10	TYLOSIN TARTRATE	23.513 gm.
TYLOSIN TARTRATE POWDER 20% -500GM (EACH GRAM CONTAINS TYLOSIN TARTRATE	1 Number	11	TYLOSIN TARTRATE	117.564 gm.

EQ. TO TYLOSIN 20%)				
TYLOSIN TARTRATE POWDER 20% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	12	TYLOSIN TARTRATE	235.128 gm.
TYLOSIN TARTRATE POWDER 99% -100GM SACHET(EACH GRAM CONTAINS TYLOSIN TARTRATE 99%)	1 Number	13	TYLOSIN TARTRATE	100 gm.
TYLOSIN TARTRATE POWDER 99% -500GM SACHET(EACH GRAM CONTAINS TYLOSIN TARTRATE 99%)	1 Number	14	TYLOSIN TARTRATE	500 gm.
TYLOSIN TARTRATE POWDER 99% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%)	1Number	15	TYLOSIN TARTRATE	1000 gm
RA concerned may take further necessary action as per above decision of NC.				

Case No.	55 / NC/3/MEET/Mar/202425/18										
Case Status	Case Approved										
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025										
HQ File Number	HQRNORM REVIW00002098AM25										
RA File Number	03AX04001846 AM24										
Licence No and Date	0311025742/25/07/2023										
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:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>TYLOSIN BOLUS 200MG (EACH</td><td>1 Number</td><td>1</td><td>TYLOSIN TARTRATE</td><td>204.00 gm.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	TYLOSIN BOLUS 200MG (EACH	1 Number	1	TYLOSIN TARTRATE	204.00 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
TYLOSIN BOLUS 200MG (EACH	1 Number	1	TYLOSIN TARTRATE	204.00 gm.							

BOLUS CONTAINS TYLOSIN 200MG)				
TYLOSIN INJECTION 5%-50 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG)	1 Number	2	TYLOSIN TARTRATE	3.056 gm.
TYLOSIN INJECTION 5%-100 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG)	1 Number	3	TYLOSIN TARTRATE	6.111 gm.
TYLOSIN TARTRATE INJECTION 20%-50 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	4	TYLOSIN TARTRATE	12.222 gm.
TYLOSIN TARTRATE INJECTION 20%-100 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	5	TYLOSIN TARTRATE	24.444 gm.
TYLOSIN TARTRATE POWDER 100%-100GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	6	TYLOSIN TARTRATE	101 gm.
TYLOSIN TARTRATE POWDER 100% -500GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	7	TYLOSIN TARTRATE	505 gm.
TYLOSIN TARTRATE POWDER 100% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	8	TYLOSIN TARTRATE	1010 gm.
TYLOSIN TARTRATE POWDER 20%-5GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	9	TYLOSIN TARTRATE	1.1756 gm.

TYLOSIN TARTRATE POWDER 20% -100GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	10	TYLOSIN TARTRATE	23.513 gm.
TYLOSIN TARTRATE POWDER 20% -500GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	11	TYLOSIN TARTRATE	117.564 gm.
TYLOSIN TARTRATE POWDER 20% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	12	TYLOSIN TARTRATE	235.128 gm.
TYLOSIN TARTRATE POWDER 99% -100GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%)	1 Number	13	TYLOSIN TARTRATE	100 gm.
TYLOSIN TARTRATE POWDER 99% -500GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%)	1 Number	14	TYLOSIN TARTRATE	500 gm.
TYLOSIN TARTRATE POWDER 99% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%)	1 Number	15	TYLOSIN TARTRATE	1000 gm.

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

Case No.	56 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002093AM25
RA File Number	03AX04002632 AM24
Licence No and Date	0311027028/12/09/2023
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.
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 250ml vial	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 500ml vial	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 50ml vial	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 250ml vial	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial
PAN Ashoxy 3% (Oxytetracycline Injection 30mg) 100ml vial	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 50ml vial	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 100ml vial	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial

Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq to Oxytetracycline 200mg) 250ml vial	1 Number	11	PROPYLENE GLYCOL	45.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 10ml viaL	1 Number	12	PROPYLENE GLYCOL	10.40 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 50ml vial	1 Number	13	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 100ml vial	1 Number	14	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 250ml vial	1 Number	15	PROPYLENE GLYCOL	260.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 500ml vial	1 Number	16	PROPYLENE GLYCOL	520.00 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 50ml viaL	1 Number	17	PROPYLENE GLYCOL	50.96 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 100ml vial	1 Number	18	PROPYLENE GLYCOL	101.92 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 50ml vial	1 Number	19	PROPYLENE GLYCOL	5.20 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 100ml vial	1 Number	20	PROPYLENE GLYCOL	10.40 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 250ml vial	1 Number	21	PROPYLENE GLYCOL	26.00 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	22	PROPYLENE GLYCOL	20.80 gm.Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml	1 Number	23	PROPYLENE GLYCOL	20.80 gm/Vial

vial				
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	24	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 5% (Tylosin Tartrate injection eq to Tylosin 50mg) 50ml vial	1 Number	25	PROPYLENE GLYCOL	10.40 gm/Vial
Ashital 10% (Closantel 10% Inj) 100ml vial	1 Number	26	PROPYLENE GLYCOL	55.12 gm/Vial
RA concerned may take further necessary action as per above decision of NC.				

Case No.	57 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00002094AM25
RA File Number	03AX04002741 AM24
Licence No and Date	0311027160/15/09/2023

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.
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 250ml vial	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial

Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 500ml vial	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 50ml vial	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 250ml vial	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial
PAN Ashoxy 3% (Oxytetracycline Injection 30mg) 100ml vial	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 50ml vial	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 100ml vial	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 250ml vial	1 Number	11	PROPYLENE GLYCOL	45.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 10ml viaL	1 Number	12	PROPYLENE GLYCOL	10.40 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 50ml vial	1 Number	13	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 100ml vial	1 Number	14	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 250ml vial	1 Number	15	PROPYLENE GLYCOL	260.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 500ml vial	1 Number	16	PROPYLENE GLYCOL	520.00 gm/Vial

Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 50ml vial	1 Number	17	PROPYLENE GLYCOL	50.96 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 100ml vial	1 Number	18	PROPYLENE GLYCOL	101.92 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 50ml vial	1 Number	19	PROPYLENE GLYCOL	5.20 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 100ml vial	1 Number	20	PROPYLENE GLYCOL	10.40 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 250ml vial	1 Number	21	PROPYLENE GLYCOL	26.00 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	22	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	23	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	24	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 5% (Tylosin Tartrate injection eq to Tylosin 50mg) 50ml vial	1 Number	25	PROPYLENE GLYCOL	10.40 gm/Vial
Ashital 10% (Closantel 10% Inj) 100ml vial	1 Number	26	PROPYLENE GLYCOL	55.12 gm/Vial

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

Case No.	58 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	AARTI INDUSTRIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006252AM24

RA File Number	03AX04003081 AM24			
Licence No and Date	0311027889/14/10/2023			
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.
2,4 DIFLUORO NITRO BENZENE (2,4 DFNB)	1 kg.	1	META DICHLORO BENZENE	1.23 kg.
		2	POTTASSIUM FLUORIDE (KF)	0.91 kg.
		3	SULFOLANE ANHYDROUS	0.10 kg.

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

Case No.	59 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006295AM24
RA File Number	03AX04003186 AM24
Licence No and Date	0311027939/17/10/2023
Norms Committee Decision:	
Committee considered the request of firm for fixation of ad-hoc norms and on the basis of information provided by the firm and it has been observed by the committee that item of export appears to be perfumery compound comes under para 4.11(b) of FTP, 2023, and the said para states that “For export of perfumes, perfumery compounds and various feed ingredients containing vitamins, no authorisation shall be issued by Regional Authority under para 4.07 of HBP and applicants shall be required to apply under para 4.06 of HBP to the Norms Committee”. Accordingly, it was decided that a clarification in this regard may be obtained from the firm as well as RA.	

Case No.	60 / NC/3/MEET/Mar/202425/18			
Case Status	Case Approved			
Party Name	VIDACARE MEDICA PRIVATE LIMITED			

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025			
HQ File Number	HQRNORM APPLY 00006329AM24			
RA File Number	03AX04003293 AM24			
Licence No and Date	0311028015/18/10/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Nov/202425/10 dated 22/11/2024 against advance authorization No. 0311031320 dated 19/02/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Item	Qty. allowed
TETRACYCLLINE HCL CAPSULE BP 250 MG EACH CAPSULE CONTAINS TETRACYCLLINE HCL BP 250MG 200000 X 10 X 10 C)	1 Number	1	TETRACYCLINE HCL BP/USP/EP	255 mg.
DEVITHRO 500 TABLETS ERYTHROMYCIN STEARATE TABLETS BP 500 MG EACH FILM COATED TABLET CONTAINS ERYTHROMYCIN STEARATE BP (693.789 MG) EQ. TO ERYTHROMYCIN BP 500 MG 35000 X 10 X 10 T)	1 Number	2	ERYTHROMYCIN STEARATE BP/USP/EP	510 mg.
DEVITHRO 250 TABLETS ERYTHROMYCIN STEARATE TABLETS BP 250 MG EACH FILM COATED TABLET CONTAINS ERYTHROMYCIN STEARATE BP (346.89 MG) EQ. TO ERYTHROMYCIN BP 250 MG 45310 X 10 X 10 T)	1 Number	3	ERYTHROMYCIN STEARATE BP/USP/EP	255 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	61 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	SWISS PARENTERALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025														
HQ File Number	HQRNORM APPLY 00006333AM24														
RA File Number	08AX04001249 AM24														
Licence No and Date	0811009697/18/10/2023														
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>CIMETIDINE INJECTION USP/BP/IP/CEP/EP/ChP 100 MG/ML,2ML</td> <td>1 Number</td> <td>1</td> <td>CIMETIDINE</td> <td>220.00 mg</td> </tr> </tbody> </table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CIMETIDINE INJECTION USP/BP/IP/CEP/EP/ChP 100 MG/ML,2ML	1 Number	1	CIMETIDINE	220.00 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.											
CIMETIDINE INJECTION USP/BP/IP/CEP/EP/ChP 100 MG/ML,2ML	1 Number	1	CIMETIDINE	220.00 mg											
RA concerned may take further necessary action as per above decision of NC.															

Case No.	62 / NC/3/MEET/Mar/202425/18														
Case Status	Case Approved														
Party Name	SWISS PARENTERALS LIMITED														
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025														
HQ File Number	HQRNORM APPLY 00006334AM24														
RA File Number	08AX04001262 AM24														
Licence No and Date	0811009700/18/10/2023														
Norms Committee Decision:															
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202425/2 dated 30/04/2024 against advance authorization No.0811008459 dated 22/06/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table 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>IMIPENEM AND CILASTATIN FOR INJECTION USP / BP / IP /CEP / EP /ChP 500 MG</td> <td>1 Number</td> <td>1</td> <td>Sterile Mixture of Imipenem and Cilastatin for Injection</td> <td>1.102 gm.</td> </tr> </tbody> </table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	IMIPENEM AND CILASTATIN FOR INJECTION USP / BP / IP /CEP / EP /ChP 500 MG	1 Number	1	Sterile Mixture of Imipenem and Cilastatin for Injection	1.102 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.											
IMIPENEM AND CILASTATIN FOR INJECTION USP / BP / IP /CEP / EP /ChP 500 MG	1 Number	1	Sterile Mixture of Imipenem and Cilastatin for Injection	1.102 gm.											
RA concerned may take further necessary action as per above decision of NC.															

Case No.	63 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006335AM24
RA File Number	05AX04002187 AM24
Licence No and Date	0511021614/18/10/2023

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.
Ciprofloxacin and Dexamethasone Sterile Otic Suspension 7.5ml (Each ml contains Ciprofloxacin 3mg. &Dexamethasone 1mg (Equivalent to 30375.00 Gm. Ciprofloxacin and 10125.00 Gm. Dexamethasone Bulk Drug)	1350000 Numbers	1	Ciprofloxacin HCL	35402.05 gm.
		2	Dexamethasone (Micronised)	10631.25 gm.

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

Case No.	64 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006356AM24
RA File Number	30AX04000323 AM24
Licence No and Date	3011004322/19/10/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202425/15 dated 28/01/2025 against advance authorization No.3011003279 dated 16/03/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
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				allowed.
VINORELBINE SOLUTION FOR INJECTION (50MG/5ML) (1 ML OF SOLUTION CONTAINS: VINORELBINE TARTRATE, EQUIVALENT TO VINORELBINE 10MG EXCIPIENTS: TARTARIC ACID, WATER FOR INJECTION)	1 Number	1	VINORELBINE TARTRATE	69.00 mg.
VINORELBINE SOLUTION FOR INJECTION (10MG/ML) (1 ML OF SOLUTION CONTAINS: VINORELBINE TARTRATE, EQUIVALENT TO VINORELBINE 10MG EXCIPIENTS: TARTARIC ACID, WATER FOR INJECTION)	1 Number	2	VINORELBINE TARTRATE	13.80 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	65 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	RUMIT LIFE CARE
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006397AM24
RA File Number	03AX04002697 AM24
Licence No and Date	0311028091/20/10/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete and Balanced chemical reactions with molecular weight and percentage yield on molar basis.	

Case No.	66 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	INTIGREAT CONSULTING SERVICES LLP
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006403AM24
RA File Number	03AX04003028 AM24
Licence No and	0311028103/23/10/2023

Date	
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Drug Manufacturing License (DML) showing approved composition of each export item. 2. Copy of Master-Batch Formula showing net content of inputs.	

Case No.	67 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	SANDOZ PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006418AM24
RA File Number	03AX04003201 AM24
Licence No and Date	0311028115/23/10/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- I. Copy of Drug Manufacturing License (DML) showing approved composition of each export item. II. Copy of Master-Batch Formula for each export item.	

Case No.	68 / NC/3/MEET/Mar/202425/18			
Case Status	Case Approved			
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025			
HQ File Number	HQRNORM APPLY 00006454AM24			
RA File Number	03AX04003224 AM24			
Licence No and Date	0311028189/26/10/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aug/202425/8 dated 28/08/2024 against advance authorization No.0311033255 dated 22/04/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
AZITHROMYCIN	1 kg.	1	AZITHROMYCIN AMINE	0.9434 kg.

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

Case No.	69 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006470AM24
RA File Number	07AX04001168 AM24
Licence No and Date	0711009558/27/10/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aug/202425/8 dated 28/08/2024 against advance authorization No.0711011049 dated 12/04/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DIRECT COMPRESSION GRANULES OF PHLOROGLUCINOL 160MG ODT PREMIX ((EACH 450 mg PREMIX CONTAINS 160 mg Phloroglucinol) contents224.28 kg))	1 kg.	1	PHLOROGLUCINOL DIHYDRATE Ph.Eur	0.359 kg.

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

Case No.	70 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006479AM24
RA File Number	03AX04003049 AM24
Licence No and Date	0311028247/27/10/2023

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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ASHOXY 20% LA / OXYVET 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack 50ML vial((EACH VIAL CONTAINS 19ML 2-pyrrolidone) (Nett Wt. of EXEMPTED MATERIAL IS 543.40 KGS) (27500 NOS))	27500 Numbers	1	2 PYRROLIDONE	570.57 kg.
ASHOXY 20% LA / OXYVET 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack 100ML vial ((EACH VIAL CONTAINS 38ML 2-pyrrolidone) (Nett Wt. of EXEMPTED MATERIAL IS 1343.68 KGS) (34000 NOS))	34000 Numbers	2	2 PYRROLIDONE	1410.86 kg.
ASHOXY 20% LA / OXYVET 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack 250ML vial((EACH VIAL CONTAINS 95ML 2-pyrrolidone) (Nett Wt. of EXEMPTED MATERIAL IS 494 KGS) (5000 NOS))	5000 Numbers	3	2 PYRROLIDONE	518.7 kg.

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

Case No.	71 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006520AM24
RA File Number	09AX04000671 AM24
Licence No and Date	0911006113/30/10/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	72 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved

Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006537AM24
RA File Number	05AX04002270 AM24
Licence No and Date	0511021818/31/10/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/May/202425/4 dated 06/06/2024 against advance authorization No.0511015737 dated 10/11/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Easyfive TT Vaccine DTwP-Hep B - Hib Pentavalent Vaccine (Each vial of 5.0ml contains 10 dose) with Vaccine Vial Monitor	100000 Vials	1	Diphtheria Bulk	13.33 Litre
		2	Tetanus Toxoid	5.23 Litre
		3	Pertussis Bulk	86.46 Litre
		4	Aluminium Phosphate Gel	6.875 kg.
		5	Electronic Temperature Data Logger	126.25 Numbers
		6	RUBBER STOPPER	1015000 Numbers
		7	VVM DOT 14	1015000 Numbers
		8	Ags Hb Purification Mabs Column	5.4 Litre
		9	Tetanus Toxoid for Conjugation	6.15 Litre

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

Case No.	73 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006566AM24
RA File Number	09AX04000607 AM24
Licence No and Date	0911006121/31/10/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Apr/202425/2 dated 30/04/2024 against advance authorization No. 0911005139 dated 01/06/2023, 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.
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.	74 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025

HQ File Number	HQRNORM APPLY 00006567AM24			
RA File Number	08AX04001381 AM24			
Licence No and Date	0811009826/31/10/2023			
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.
Nystatin Cream USP, 100000 units/gm, 15gm (15gm Tube) (Each gram Contains: 100,000 USP Nystatin Units in an aqueous, cream base. Net content of Nystatin should not be less than 57.785 Kg in export item)	240000 Numbers	1	Nystatin (Nystatin Micronized)	58.96 kg.
Nystatin Cream USP, 100000 units/gm, 30gm (30gm Tube) (Each gram Contains: 100,000 USP Nystatin Units in anaqueous, cream base. Net content of Nystatin should not be less than 247.994 Kg in export item)	515000 Numbers	2	Nystatin (Nystatin Micronized)	252.96 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	75 / NC/3/MEET/Mar/202425/18			
Case Status	Case Approved			
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025			
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 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.

Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 250ml vial	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 500ml vial	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 50ml vial	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 250ml vial	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial
PAN Ashoxy 3% (Oxytetracycline Injection 30mg) 100ml vial	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 50ml vial	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 100ml vial	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 250ml vial	1 Number	11	PROPYLENE GLYCOL	45.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 10ml viaL	1 Number	12	PROPYLENE GLYCOL	10.40 gm/Vial

Ashiver 1% (Ivermectin 10 Mg Injection) 50ml vial	1 Number	13	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 100ml vial	1 Number	14	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 250ml vial	1 Number	15	PROPYLENE GLYCOL	260.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 500ml vial	1 Number	16	PROPYLENE GLYCOL	520.00 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 50ml vial	1 Number	17	PROPYLENE GLYCOL	50.96 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 100ml vial	1 Number	18	PROPYLENE GLYCOL	101.92 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 50ml vial	1 Number	19	PROPYLENE GLYCOL	5.20 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 100ml vial	1 Number	20	PROPYLENE GLYCOL	10.40 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 250ml vial	1 Number	21	PROPYLENE GLYCOL	26.00 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	22	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	23	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	24	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 5% (Tylosin Tartrate injection	1 Number	25	PROPYLENE GLYCOL	10.40 gm/Vial

eq to Tylosin 50mg) 50ml vial				
Ashital 10% (Closantel 10% Inj) 100ml vial	1 Number	26	PROPYLENE GLYCOL	55.12 gm/Vial

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

Case No.	76 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006571AM24
RA File Number	03AX04003274 AM24
Licence No and Date	0311028380/01/11/2023

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.
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 250ml vial	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 500ml vial	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial
Ashoxy 10% (Oxytetracycline Hydrochloride Injection 50mg) 500ml vial	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial

Injection 100mg) 50ml vial				
Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 250ml vial	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial
PAN Ashoxy 3% (Oxytetracycline Injection 30mg) 100ml vial	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 50ml vial	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 100ml vial	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 250ml vial	1 Number	11	PROPYLENE GLYCOL	45.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 10ml viaL	1 Number	12	PROPYLENE GLYCOL	10.40 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 50ml vial	1 Number	13	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 100ml vial	1 Number	14	PROPYLENE GLYCOL	104.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 250ml vial	1 Number	15	PROPYLENE GLYCOL	260.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 500ml vial	1 Number	16	PROPYLENE GLYCOL	520.00 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 50ml viaL	1 Number	17	PROPYLENE GLYCOL	50.96 gm/Vial

Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 100ml vial	1 Number	18	PROPYLENE GLYCOL	101.92 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 50ml vial	1 Number	19	PROPYLENE GLYCOL	5.20 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 100ml vial	1 Number	20	PROPYLENE GLYCOL	10.40 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 250ml vial	1 Number	21	PROPYLENE GLYCOL	26.00 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	22	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	23	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial	1 Number	24	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 5% (Tylosin Tartrate injection eq to Tylosin 50mg) 50ml vial	1 Number	25	PROPYLENE GLYCOL	10.40 gm/Vial
Ashital 10% (Closantel 10% Inj) 100ml vial	1 Number	26	PROPYLENE GLYCOL	55.12 gm/Vial

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

Case No.	77 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006591AM24
RA File Number	03AX04003361 AM24
Licence No and	0311028403/02/11/2023

Date

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed
TYLOSIN BOLUS 200MG(TYLOSIN BOLUS 200MG (EACH BOLUS CONTAINS TYLOSIN 200MG)	1 Number	1	TYLOSIN TARTRATE	204.00 gm.
TYLOSIN INJECTION 5%-50 ML (TYLOSIN INJECTION 5%-50 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG)	1 Number	2	TYLOSIN TARTRATE	3.056 gm.
TYLOSIN INJECTION 5%-100 ML (TYLOSIN INJECTION 5%-100 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG)	1 Number	3	TYLOSIN TARTRATE	6.111 gm.
TYLOSIN TARTRATE INJECTION 20%-50 ML(TYLOSIN TARTRATE INJECTION 20%-50 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	4	TYLOSIN TARTRATE	12.222 gm.
TYLOSIN TARTRATE INJECTION 20%-100 ML(TYLOSIN TARTRATE INJECTION 20%-100 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	5	TYLOSIN TARTRATE	24.444 gm.
TYLOSIN TARTRATE POWDER 100%-100GM SACHET(TYLOSIN TARTRATE POWDER 100%-100GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	6	TYLOSIN TARTRATE	101 gm.
TYLOSIN TARTRATE POWDER 100% - 500GM SACHET(TYLOSIN TARTRATE	1 Number	7	TYLOSIN TARTRATE	505 gm.

POWDER 100% -500GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)				
TYLOSIN TARTRATE POWDER 100% - 1KG JAR(TYLOSIN TARTRATE POWDER 100% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%))	1 Number	8	TYLOSIN TARTRATE	1010 gm.
TYLOSIN TARTRATE POWDER 20%-5GM (TYLOSIN TARTRATE POWDER 20%-5GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%))	1 Number	9	TYLOSIN TARTRATE	1.1756 gm.
TYLOSIN TARTRATE POWDER 20% - 100GM (TYLOSIN TARTRATE POWDER 20% -100GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%))	1 Number	10	TYLOSIN TARTRATE	23.513 gm.
TYLOSIN TARTRATE POWDER 20% - 500GM (TYLOSIN TARTRATE POWDER 20% -500GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%))	1 Number	11	TYLOSIN TARTRATE	117.564 gm.
TYLOSIN TARTRATE POWDER 20% -1KG JAR (TYLOSIN TARTRATE POWDER 20% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%))	1 Number	12	TYLOSIN TARTRATE	235.128 gm.
TYLOSIN TARTRATE POWDER 99% - 100GM SACHET(TYLOSIN TARTRATE POWDER 99% -100GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%))	1 Number	13	TYLOSIN TARTRATE	100 gm.
TYLOSIN TARTRATE POWDER 99% -	1 Number	14	TYLOSIN TARTRATE	500 gm.

500GM SACHET(TYLOSIN TARTRATE POWDER 99% -500GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%))				
TYLOSIN TARTRATE POWDER 99% -1KG JAR(TYLOSIN TARTRATE POWDER 99% - 1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%))	1 Number	15	TYLOSIN TARTRATE	1000 gm

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

Case No.	78 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 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.
TYLOSIN BOLUS 200MG(TYLOSIN BOLUS 200MG (EACH BOLUS CONTAINS TYLOSIN 200MG))	1 Number	1	TYLOSIN TARTRATE	204.00 gm.
TYLOSIN INJECTION 5%-50 ML (TYLOSIN INJECTION 5%-50 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG))	1 Number	2	TYLOSIN TARTRATE	3.056 gm.
TYLOSIN INJECTION 5%-100 ML (TYLOSIN INJECTION 5%-100 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG))	1 Number	3	TYLOSIN TARTRATE	6.111 gm.

TYLOSIN TARTRATE INJECTION 20%-50 ML(TYLOSIN TARTRATE INJECTION 20%-50 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	4	TYLOSIN TARTRATE	12.222 gm.
TYLOSIN TARTRATE INJECTION 20%-100 ML(TYLOSIN TARTRATE INJECTION 20%-100 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	5	TYLOSIN TARTRATE	24.444 gm.
TYLOSIN TARTRATE POWDER 100%-100GM SACHET(TYLOSIN TARTRATE POWDER 100%-100GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	6	TYLOSIN TARTRATE	101 gm.
TYLOSIN TARTRATE POWDER 100% - 500GM SACHET(TYLOSIN TARTRATE POWDER 100% -500GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	7	TYLOSIN TARTRATE	505 gm.
TYLOSIN TARTRATE POWDER 100% - 1KG JAR(TYLOSIN TARTRATE POWDER 100% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	8	TYLOSIN TARTRATE	1010 gm.
TYLOSIN TARTRATE POWDER 20%-5GM (TYLOSIN TARTRATE POWDER 20%-5GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	9	TYLOSIN TARTRATE	1.1756 gm.
TYLOSIN TARTRATE POWDER 20% - 100GM (TYLOSIN TARTRATE POWDER 20% -100GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%)	1 Number	10	TYLOSIN TARTRATE	23.513 gm.

TYLOSIN TARTRATE POWDER 20% - 500GM (TYLOSIN TARTRATE POWDER 20% -500GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%))	1 Number	11	TYLOSIN TARTRATE	117.564 gm.
TYLOSIN TARTRATE POWDER 20% -1KG JAR (TYLOSIN TARTRATE POWDER 20% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%))	1 Number	12	TYLOSIN TARTRATE	235.128 gm.
TYLOSIN TARTRATE POWDER 99% - 100GM SACHET(TYLOSIN TARTRATE POWDER 99% -100GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%))	1 Number	13	TYLOSIN TARTRATE	100 gm.
TYLOSIN TARTRATE POWDER 99% - 500GM SACHET(TYLOSIN TARTRATE POWDER 99% -500GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%))	1 Number	14	TYLOSIN TARTRATE	500 gm.
TYLOSIN TARTRATE POWDER 99% -1KG JAR(TYLOSIN TARTRATE POWDER 99% - 1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%))	1 Number	15	TYLOSIN TARTRATE	1000 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	79 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 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.
TYLOSIN BOLUS 200MG(TYLOSIN BOLUS 200MG (EACH BOLUS CONTAINS TYLOSIN 200MG)	1 Number	1	TYLOSIN TARTRATE	204.00 gm.
TYLOSIN INJECTION 5%-50 ML (TYLOSIN INJECTION 5%-50 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG)	1 Number	2	TYLOSIN TARTRATE	3.056 gm.
TYLOSIN INJECTION 5%-100 ML (TYLOSIN INJECTION 5%-100 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN BASE 50MG)	1 Number	3	TYLOSIN TARTRATE	6.111 gm.
TYLOSIN TARTRATE INJECTION 20%-50 ML(TYLOSIN TARTRATE INJECTION 20%-50 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	4	TYLOSIN TARTRATE	12.222 gm.
TYLOSIN TARTRATE INJECTION 20%-100 ML(TYLOSIN TARTRATE INJECTION 20%-100 ML (EACH ML CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 200MG)	1 Number	5	TYLOSIN TARTRATE	24.444 gm.
TYLOSIN TARTRATE POWDER 100%-100GM SACHET (TYLOSIN TARTRATE POWDER 100%-100GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	6	TYLOSIN TARTRATE	101 gm.
TYLOSIN TARTRATE POWDER 100% - 500GM SACHET(TYLOSIN TARTRATE POWDER 100% -500GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%)	1 Number	7	TYLOSIN TARTRATE	505 gm.

TYLOSIN TARTRATE POWDER 100% - 1KG JAR(TYLOSIN TARTRATE POWDER 100% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE 100%))	1 Number	8	TYLOSIN TARTRATE	1010 gm.
TYLOSIN TARTRATE POWDER 20%-5GM (TYLOSIN TARTRATE POWDER 20%-5GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%))	1 Number	9	TYLOSIN TARTRATE	1.1756 gm.
TYLOSIN TARTRATE POWDER 20% - 100GM (TYLOSIN TARTRATE POWDER 20% -100GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%))	1 Number	10	TYLOSIN TARTRATE	23.513 gm.
TYLOSIN TARTRATE POWDER 20% - 500GM (TYLOSIN TARTRATE POWDER 20% -500GM (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%))	1 Number	11	TYLOSIN TARTRATE	117.564 gm.
TYLOSIN TARTRATE POWDER 20% -1KG JAR (TYLOSIN TARTRATE POWDER 20% -1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE EQ. TO TYLOSIN 20%))	1 Number	12	TYLOSIN TARTRATE	235.128 gm.
TYLOSIN TARTRATE POWDER 99% - 100GM SACHET(TYLOSIN TARTRATE POWDER 99% -100GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%))	1 Number	13	TYLOSIN TARTRATE	100 gm.
TYLOSIN TARTRATE POWDER 99% - 500GM SACHET(TYLOSIN TARTRATE POWDER 99% -500GM SACHET (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%))	1 Number	14	TYLOSIN TARTRATE	500 gm.

TYLOSIN TARTRATE POWDER 99% -1KG JAR(TYLOSIN TARTRATE POWDER 99% - 1KG JAR (EACH GRAM CONTAINS TYLOSIN TARTRATE 99%))	1 Number	15	TYLOSIN TARTRATE	1000 gm.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	80 / NC/3/MEET/Mar/202425/18			
Case Status	Case Approved			
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025			
HQ File Number	HQRNORM APPLY 00006633AM24			
RA File Number	03AX04003515 AM24			
Licence No and Date	0311028487/04/11/2023			
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.
N Propyl Acetate	1000000 kg.	1	Acetic Acid (Glacial)	609000 kg.
		2	N-Propanol	605000 kg.

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

Case No.	81 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202425/2 dated 28/01/2025 against advance authorization No.3411003627 dated 26/04/2023 , 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.
CLOMIPRAMINE HCL CAP USP 25 MG	1 Number	1	Clomipramine Hydrochloride USP	25.50 mg.
		2	Microcrystalline Cellulose (Avicel PH 301)	148.80 mg.
		3	Pregelatinized starch (Starch 1500 LM)	39.60 mg.
		4	Colloidal silicon dioxide (Aerosil 200 Pharma)	2.20 mg.
		5	Magnesium Stearate (Vegetable Source)	4.40 mg.
CLOMIPRAMINE HCL CAP USP 50 MG	1 Number	6	Clomipramine Hydrochloride USP	51.00 mg.
		7	Microcrystalline Cellulose (Avicel PH 301)	210.70 mg.
		8	Pregelatinized starch (Starch 1500 LM)	59.40 mg.
		9	Colloidal silicon dioxide (Aerosil 200 Pharma)	3.30 mg.
		10	Magnesium Stearate (Vegetable Source)	6.60 mg.
CLOMIPRAMINE HCL CAP USP 75 MG	1 Number	11	Clomipramine Hydrochloride USP	76.50 mg.
		12	Microcrystalline Cellulose	205.45 mg.

			(Avicel PH 301)	
		13	Pregelatinized starch (Starch 1500 LM)	63.90 mg.
		14	Colloidal silicon dioxide (Aerosil 200 Pharma)	3.55 mg.
		15	Magnesium Stearate (Vegetable Source)	7.10 mg.

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

Case No.	82 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	RALLIS INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006775AM24
RA File Number	03AX04003377 AM24
Licence No and Date	0311028623/09/11/2023
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Yield for first stage of reaction. 2. Justification of low yield of 48% in second stage. 3. Quantity of DMSO as solvent and recovery thereof. 4. Balanced chemical reaction withy stichometric balance on molar basis.	

Case No.	83 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 and TE was requested to expedite his comments.

Case No.	84 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Jan/202425/15 dated 28/01/2025 against advance authorization No.3411003627 dated 26/04/2023, 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.
CLOMIPRAMINE HCL CAP USP 25 MG	1 Number	1	Clomipramine Hydrochloride USP	25.50 mg.
		2	Microcrystalline Cellulose (Avicel PH 301)	148.80 mg.
		3	Pregelatinized starch (Starch 1500 LM)	39.60 mg.
		4	Colloidal silicon dioxide (Aerosil 200 Pharma)	2.20 mg.
		5	Magnesium Stearate (Vegetable Source)	4.40 mg.
CLOMIPRAMINE HCL CAP USP 50 MG	1 Number	6	Clomipramine Hydrochloride USP	51.00 mg.
		7	Microcrystalline Cellulose	210.70 mg.

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

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

Case No.	85 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Vonoprazan Fumarate	1 kg.	1	2-FLUORO ACETOPHENONE	0.860 kg.
		2	Pyridine 3 sulfonyl chloride	0.856 kg.
		3	Tetrahydrofuran	3.29 kg.
		4	Methylene Di Chloride	3.80 kg.
		5	Sodium Borohydrate	0.22 kg.
		6	Potassium Carbonate	0.66 kg.
		7	Di Methyl sulfoxide	1.00 kg.

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

Case No.	86 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 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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Dapagliflozin Propanediol Monohydrate	1 kg.	1	Methanol	2.00 kg.
		2	(S)-(+)-1,2-PROPANEDIOL	0.20 kg.
		3	n-Heptane	2.00 kg.
		4	Lithium Metal	0.124 kg.
		5	Methylene Di Chloride	3.00 kg.
		6	Acetonitrile	2.10 kg.
		7	TETRA HYDRO FURAN (THF)	2.50 kg.
		8	SODIUM BOROHYDRIDE	0.20 kg.

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

Case No.	87 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006896AM24
RA File Number	08AX04001535 AM24
Licence No and Date	0811009983/17/11/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	88 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00006966AM24
RA File Number	08AX04001564 AM24
Licence No and Date	0811010011/22/11/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Feb/202324/23 dated 19/02/2024 against advance authorization No.0810145144 dated 01/05/2019, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Indoline	1 kg.	1	O CHLOROBENZYL CYANIDE	2.20 kg.
		2	TOLUENE	1.00 kg.

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

Case No.	89 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	MEONE HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202425/23 dated 28/01/2025 against advance authorization No.0411005383 dated 10/05/2023, 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.
FOSCARNET SODIUM INJECTION 250 ML (24mg/ml which contain 88.33% strength of import item)	1 Number	1	Foscarnet Sodium API (Foscarnet Sodium Hexahydrate EP 8.0	6.30 gm.

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

Case No.	90 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025			
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 case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202425/15 dated 28/01/2025 against advance authorization No.0711006773 dated 16/03/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Calcium Dobesilate Monohydrate BP/ Calcium Dobesilate Monohydrate Eur.Ph / Calcium Dobesilate	1 kg.	1	Hydroquinone	0.631 kg.
Etamsylate / Etamsylate EP	1 kg.	2	Hydroquinone	0.527 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	91 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-	
1. A balance chemical reaction indicting molecular weight of reactants and products with yield of the reaction.	
2. Difference between import and export based on end use.	

Case No.	92 / NC/3/MEET/Mar/202425/18			
Case Status	Case Deferred			
Party Name	R.L.FINE CHEM PRIVATE LIMITED			

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 and TE was requested to expedite his comments.	

Case No.	93 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00007141AM24
RA File Number	03AX04003919 AM24
Licence No and Date	0311029038/01/12/2023

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.
Assurity Plus SPOT ON (For Small Cat) (Pack size 0.4ml x 6 pipettes), (Each ml contains: Imidacloprid 100mg, Net Weight = 480 Grams)	2000 Numbers	1	Imidacloprid	60.064 kg.
Assurity Plus SPOT ON (For Large Cat) (Pack size 0.8ml x 6 pipettes),(Each ml contains: Imidacloprid 100mg, Net Weight = 960 Grams)	2000 Numbers	2		
Assurity Plus SPOT ON (For Small Dog) (Pack size 0.4ml x 6 Pipettes),(Each ml contains: Imidacloprid 100mg, Net Weight = 480 Grams)	2000 Number	3		
Assurity Plus SPOT ON (For Medium Dog) (Pack size 1ml x 6 Pipettes),(Each ml contains: Imidacloprid 100mg , Net Weight = 1200 Grams)	2000 Numbers	4		
Assurity Plus SPOT ON (For Large Dog) (Pack size 2.5ml x 6 Pipettes),(Each ml contains: Imidacloprid 100mg , Net Weight = 3000 Grams)	2000 Numbers	5		

Assurity Plus SPOT ON (For Extra Large Dog) (Pack size 4ml x 6 Pipettes),(Each ml contains: Imidacloprid 100mg , Net Weight = 7200 Grams)	3000 Numbers	6		
Banflea Plus SPOT ON (For Small Cat) (Pack size 0.4ml x 6 Pipettes)(Each ml contains: Imidacloprid 91mg, Net Weight = 218.40 Grams)	1000 Numbers	7		
Banflea Plus SPOT ON (For Large Cat) (Pack size 0.8ml x 6 Pipettes),(Each ml contains: Imidacloprid 91mg, Net Weight = 436.80 Grams)	1000 Numbers	8		
Banflea Plus SPOT ON (For Small Dog) (Pack size 0.4ml x 6 Pipettes)(Each ml contains: Imidacloprid 91mg, Net Weight = 262.08 Grams)	1200 Numbers	9		
Banflea Plus Spot on for Dog (For Medium Dog) (Pack size 1ml x 6 Pipettes),(Each ml contains: Imidacloprid 91mg, Net Weight = 546.00 Grams)	1000 Numbers	10		
Banflea Plus SPOT ON (For Large Dog) (Pack size 2.5ml x 6 Pipettes),(Each ml contains: Imidacloprid 91mg, Net Weight = 1365.00 Grams)	1000 Numbers	11		
Banflea Plus Spot on (For Extra Large Dog) (Pack size 4ml x 6 Pipettes),(Each ml contains: Imidacloprid 91mg, Net Weight = 2184.00 Grams)	1000 Numbers	12		
Banflea II Plus Spot on (For Extra Large Dog) (Pack size 4ml x 6 Pipettes),(Each ml contains: Imidacloprid 88mg, Net Weight = 2112.00 Grams)	1000 Numbers	13		
Banflea II Plus Spot on (For Large Dog) (Pack size 2.5ml x 6 Pipettes),(Each ml contains: Imidacloprid 88mg, Net Weight = 1320.00 Grams)	1000 Numbers	14		
Banflea II Spot on (For Medium Dog) (Pack size 1ml x 6 Pipettes),(Each ml contains: Imidacloprid 88mg, Net Weight = 633.60 Grams)	1200 Numbers	15		
Banflea II Plus Spot on (For Small Dog) (Pack size 0.4ml x 6 Pipettes),(Each ml contains: Imidacloprid 88mg, Net Weight = 253.44 Grams)	1200 Numbers	16		

Nugard Spot On for Puppies and Dogs up to 4kg (Pack size 0.4ml x 1 Pipettes)(Each Litre contains: Imidacloprid 100mg, Net Weight = 40.00 Grams)	1000 Numbers	17		
Nugard Spot On for Puppies and Dogs up to 4kg (Pack size 0.4ml x 3 Pipettes),(Each Litre ml contains: Imidacloprid 100mg, Net Weight = 240.00 Grams)	2000 Numbers	18		
Nugard Spot On for Puppies and Dogs up to 4kg (Pack size 0.4ml x 6 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 600.00 Grams)	2500 Numbers	19		
Nugard Spot On for Dogs 4-10kg (Pack size 1ml x 1 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 100.00 Grams)	1000 Numbers	20		
Nugard Spot On for Dogs 4-10kg (Pack size 1ml x 3 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 750.00 Grams)	2500 Numbers	21		
Nugard Spot On for Dogs 4-10kg (Pack size 1ml x 6 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 2400.00 Grams)	4000 Numbers	22		
Nugard Spot On for Dogs 10- 25kg (Pack size 2.5ml x 1 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 250.00 Grams)	1000 Numbers	23		
Nugard Spot On for Dogs 10- 25kg (Pack size 2.5ml x 3 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 1875.00 Grams)	2500 Numbers	24		
Nugard Spot On for Dogs 10- 25kg (Pack size 2.5ml x 6 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 6000.00 Grams)	4000 Numbers	25		
Nugard Spot On for Dogs over 25kg (Pack size 4ml x 1 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 400.00 Grams)	1000 Numbers	26		

Nugard Spot On for Dogs over 25kg (Pack size 4ml x 3 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 2400.00 Grams)	2000 Numbers	27		
Nugard Spot On for Dogs over 25kg (Pack size 4ml x 6 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 14400.00 Grams)	6000 Numbers	28		
Nugard Spot On for kittens and cats up to 4 kg (Pack size 0.4ml x 1 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 40.00 Grams)	1000 Numbers	29		
Nugard Spot On for kittens and cats up to 4 kg (Pack size 0.4ml x 3 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 300.00 Grams)	2500 Numbers	30		
Nugard Spot On for kittens and cats up to 4 kg (Pack size 0.4ml x 6 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 960.00 Grams)	4000 Numbers	31		
Nugard Spot On Cats over 4 kg (Pack size 0.8ml x 1 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 80.00 Grams)	1000 Numbers	32		
Nugard Spot On Cats over 4 kg (Pack size 0.8ml x 3 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 600.00 Grams)	2500 Numbers	33		
Nugard Spot On Cats over 4 kg (Pack size 0.8ml x 6 Pipettes),(Each Litre contains: Imidacloprid 100mg, Net Weight = 4800.00 Grams)	10000 Numbers	34		
RA concerned may take further necessary action as per above decision of NC.				

Case No.	94 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	VIDACARE MEDICA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 480 MG 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 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.	95 / NC/3/MEET/Mar/202425/18										
Case Status	Case Approved										
Party Name	AARTI INDUSTRIES LTD										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025										
HQ File Number	HQRNORM APPLY 00007168AM24										
RA File Number	03AX04003918 AM24										
Licence No and Date	0311029075/04/12/2023										
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:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>AOB 98 (N-Benzyl methylamine)</td><td>1 kg.</td><td>1</td><td>ANILINE</td><td>0.92 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	AOB 98 (N-Benzyl methylamine)	1 kg.	1	ANILINE	0.92 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
AOB 98 (N-Benzyl methylamine)	1 kg.	1	ANILINE	0.92 kg.							

		2	METHANOL	0.314 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	96 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 case as per agenda and it has been observed that as per Drug Manufacturing License, export items No. 5 & 6 are Sex Hormone Gel for external use and not matching with description giving in the application. Therefore, it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with sample.	

Case No.	97 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00007192AM24
RA File Number	34AX04000671 AM24
Licence No and Date	3411004398/04/12/2023
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Master Batch Formula for each export showing net content of each import.	

Case No.	98 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00007195AM24
RA File Number	34AX04000621 AM24
Licence No and	3411004402/04/12/2023

Date	
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Master Batch Formula for each export showing net content of each import.	

Case No.	99 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00007220AM24
RA File Number	03AX04003769 AM24
Licence No and Date	0311029140/06/12/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Drug Manufacturing License (DML). 2. Copy of Master-Batch Formula	

Case No.	100 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	S KANT HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
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 and TE was requested to expedite his comments.	

Case No.	101 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00007339AM24
RA File Number	03AX04004064 AM24
Licence No and	0311029280/12/12/2023

Date

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Item	Qty. allowed
Mometasone Furoate & Azelastine Hydrochloride Nasal Spray (150MD) ((DIRNELID AZ/ MOMATE AZ) 150 MDI (Each Spray Deliver Mometasone Furoate 50mcg and Azelastine Hydrochloride 140 mcg) (Net Wt. of Import Sr. No. 1 is 3750 Grams and Import Sr. No.2 is 10500 Grams))	500000 Numbers	1	Mometasone Furoate BP (Micronized)	3825 grams
Mometasone Furoate & Azelastine Hydrochloride Nasal Spray (75MD) ((DIRNELID AZ MOMATE AZ) 75 MDI (Each Spray Deliver Mometasone Furoate 50mcg and Azelastine Hydrochloride 140 mcg) (Net Wt. of Import Sr. No. 1 is 750 Grams and Import Sr. No.2 is 2100 Grams))	200000 Numbers	2	Azelastine Hydrochloride BP	2142 grams.

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

Case No.	102 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00007347AM24
RA File Number	05AX04002833 AM24
Licence No and Date	0511022620/12/12/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	103 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00007728AM24
RA File Number	09AX04000875 AM24
Licence No and Date	0911006481/03/01/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it has been observed that the firm has applied for import of intermediate (item No.2) and its raw material (item No.3) and since solvents are mix-up for import item No. 1 and 2, no norms can be worked out in the present form, therefore, as per the advice of the TE, it was decided to call for attending <u>Personal Hearing</u> before Norms Committee with justification and details and documentary evidence of actual import.	

Case No.	104 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00008252AM24
RA File Number	09AX04000962 AM24
Licence No and Date	0911006666/31/01/2024
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	105 / NC/3/MEET/Mar/202425/18			
Case Status	Case Approved			
Party Name	AMI ORGANICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025			
HQ File Number	HQRNORM REVIW00001910AM25			
RA File Number	52AX04000349 AM24			
Licence No and Date	5211007412/15/02/2024			
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.

1,2,4 - TRIAZOLO (4,3-a) PYRIDIN -3 (2H) - ONE - 98% MIN.	1 kg.	1	SEMICARBAZIDE HCL - 99% MIN	2.806 kg.
		2	2-CHLORO PYRIDINE	1.37 kg.
		3	ETHYLENE GLYCOL MONOETHYL ETHER/ 2-ETHOXY ETHANOL	1.45 kg.

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

Case No.	106 / NC/3/MEET/Mar/202425/18
Case Status	Case Rejected
Party Name	EAST AFRICAN INDIA OVERSEAS
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM REVIW00001665AM25
RA File Number	05AX04003662 AM24
Licence No and Date	0511024074/26/02/2024
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to <u>reject</u> the case maintaining the status quo.	

Case No.	107 / NC/3/MEET/Mar/202425/18			
Case Status	Case Approved			
Party Name	TORRENT PHARMACEUTICALS LTD			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025			
HQ File Number	HQRNORM APPLY 00002126AM25			
RA File Number	08AX04000638 AM25			
Licence No and Date	0811012201/24/07/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/13 dated 07/01/2025 against advance authorization No. 0811012198 dated 24/07/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

CANDESARTAN CILEXETIL 2 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 2 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 0.180 KG IN EXPORT ITEM)	1 Number	1	CANDESARTAN CILEXETIL PH.EUR	2.04 mg.
CANDESARTAN CILEXETIL 4 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 4 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 1.440 KG IN EXPORT ITEM)	1 Number	2	CANDESARTAN CILEXETIL PH.EUR	4.08 mg.
CANDESARTAN CILEXETIL 8 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 8 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 5.760 KG IN EXPORT ITEM)	1 Number	3	CANDESARTAN CILEXETIL PH.EUR	8.16 mg.
CANDESARTAN CILEXETIL 16 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 16 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 399.226 KG IN EXPORT ITEM)	1 Number	4	CANDESARTAN CILEXETIL PH.EUR	16.32 mg.
CANDESARTAN CILEXETIL 32 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 32 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 14.400 KG IN EXPORT ITEM)	1 Number	5	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZID E	1 Number	6	CANDESARTAN CILEXETIL PH.EUR	8.16 mg.

TABLETS 8 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 8 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 2.520 KG IN EXPORT ITEM)				
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 16 MG +12.5 MG (EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 16 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 46.800 KG IN EXPORT ITEM)	1 Number	7	CANDESARTAN CILEXETIL PH.EUR	16.32 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 11.520 KG IN EXPORT ITEM)	1 Number	8	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32 MG +25 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 25 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 11.520 KG IN EXPORT ITEM)	1 Number	9	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.

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

Case No.	108 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002138AM25
RA File Number	03AX04002062 AM25
Licence No and Date	0311035818/25/07/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Sep/2024259 dated 10/10/2024 against advance authorization No. 0311020797 dated 19/01/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Fenofibrate Bulk Granulate	1 kg.	1	Fenofibrate Micronized IH/Ph.Eur	0.3155 kg.
		2	Hypromellose (2910, 3 cps) Ph. Eur	0.0625 kg.
		3	Docusate Sodium Ph.Eur	0.0062 kg.
		4	Sucrose Ph.Eur	0.3124 kg.
		5	Sodium Lauril Sulfate Ph.Eur	0.0216 kg.
		6	Lactose Monohydrate Ph.Eur	0.2804 kg.

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

Case No.	109 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	BROOKS STERISCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002147AM25
RA File Number	34AX04000341 AM25
Licence No and Date	3411005213/25/07/2024
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Jun/202425/6 dated 01/07/2024 against advance authorization No.3411003857 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.
Meropenem for Injection USP 500 mg	1 Number	1	Sterile Meropenem with Sodium Carbonate USP	0.645 gm/500 mg Injection
Meropenem for Injection USP 1000 mg	1 Number	2	Sterile Meropenem with Sodium Carbonate USP	1.29 gm/1 gm Injection

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

Case No.	110 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002151AM25
RA File Number	03AX04002072 AM25
Licence No and Date	0311035851/26/07/2024

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.
ASHOXY 20% LA / OXYVET 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack 50ML vial((EACH VIAL CONTAINS 19ML 2-pyrrolidone) (Nett Wt. of EXEMPTED MATERIAL IS 1086.80 KGS) (55000 NOS))	55000 Numbers	1	2 PYRROLIDONE	1141.14 kg.
ASHOXY 20% LA / OXYVET 20% LA (OXYTETRACYCLINE INJECTABLE	68000 Numbers	2	2 PYRROLIDONE	2821.73 kg.

SOLUTION 20% LONG ACTING) Pack 100ML vial((EACH VIAL CONTAINS 38ML 2-pyrrolidone) (Nett Wt. of EXEMPTED MATERIAL IS 2687.36 KGS) (68000 NOS))				
ASHOXY 20% LA / OXYVET 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack 250ML vial((EACH VIAL CONTAINS 95ML 2-pyrrolidone) (Nett Wt. of EXEMPTED MATERIAL IS 988.00KGS) (10000 NOS))	10000 Numbers	3	2 PYRROLIDONE	1037.4 kg.

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

Case No.	111 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002152AM25
RA File Number	52AX04000118 AM25
Licence No and Date	5211009121/26/07/2024

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.
CLOBETASOL PROPIONATE	1 kg.	1	BETAMETHASONE	0.95 kg.

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

Case No.	112 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002169AM25
RA File Number	03AX04002099 AM25

Licence No and Date	0311035876/26/07/2024			
Norms Committee Decision:				
Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jan/202425/15 dated 28/01/2025 against advance authorization No.0311022155 dated 15/03/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Carbamazepine Extended-Release Tablets USP 100 mg.(Each tablet contains (i) Carbamazepine 100 mg. (ii) CelluloseAcetate(CA-320S)-Eastman35.04mg.(iii)Eastman(TMCelluloseAcetate(CA398-10 NF / EP)- 5.28 mg Net content (i) 750 Kg (ii)262.80 Kg (iii) 39.60 Kg.)	1 Number	1	Carbamazepine	102.00 mg.
		2	Cellulose Acetate (CA-320S) Eastman	29.20 mg.
		3	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.
Carbamazepine Extended-Release Tablets USP 200 mg.(Each tablet contains (i) Carbamazepine 200 mg. (ii) Cellulose Acetate (CA-320S) -Eastman 35.04 mg. (iii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 5.28 mg Net content (i) 550 kg (ii) 96.36 Kg (iii) 14.52 Kg.)	1 Number	4	Carbamazepine	204.00 mg.
		5	Cellulose Acetate (CA-320S) Eastman	29.20 mg.
		6	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.
Carbamazepine Extended-Release Tablets USP 400 mg.(Each tablet contains (i) Carbamazepine 400 mg. (ii) Cellulose Acetate (CA-320S) -Eastman 26.28 mg. (iii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 3.96 mg Net content (i) 666 Kg. (ii) 43.76 Kg (ii) 6.59 Kg.)	1 Number	7	Carbamazepine	4408.00 mg.
		8	Cellulose Acetate (CA-320S) Eastman	29.20 mg.
		9	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.

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

Case No.	113 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	CHEMPLAST SANMAR LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002173AM25
RA File Number	04AX04000360 AM25
Licence No and Date	0411007898/26/07/2024

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.
(4R)-2-oxooxazolidine-4-carboxylic acid (COX)	1 kg.	1	D-Serine ((R)-2-amino-3-hydroxypropanoic acid)	1.073 kg.
		2	Potassium methoxide 32% in methanol	2.240 kg.
		3	Methyl Isobutyl Ketone (MIBK)	0.330 kg.

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

Case No.	114 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	AMI LIFESCIENCES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002190AM25
RA File Number	34AX04000349 AM25
Licence No and Date	3411005224/29/07/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export

product/import item in meeting No. NC/3/MEET/Oct/202324/15 dated 13/10/2023 against advance authorization No.0911001652 dated 29/09/2021, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Vonoprazan Fumarate	1 kg.	1	5-(2-Fluorophenyl)-1H-pyrrole-3-carboxaldehyde	0.757 kg.
		2	Pyridine-3-sulfonyl chloride	0.856 kg.

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

Case No.	115 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	AMI LIFESCIENCES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002191AM25
RA File Number	34AX04000348 AM25
Licence No and Date	3411005225/29/07/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	116 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	AMI LIFESCIENCES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002192AM25
RA File Number	34AX04000347 AM25
Licence No and Date	3411005226/29/07/2024
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.
Bisbentiamine	1 kg.	1	Thiamine Hydrochloride	0.673 kg.

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

Case No.	117 / NC/3/MEET/Mar/202425/18
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002205AM25
RA File Number	05AX04001339 AM25
Licence No and Date	0511026904/30/07/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	118 / NC/3/MEET/Mar/202425/18															
Case Status	Case Approved															
Party Name	ALEMBIC PHARMACEUTICALS LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025															
HQ File Number	HQRNORM APPLY 00002208AM25															
RA File Number	08AX04000455 AM25															
Licence No and Date	0811012244/30/07/2024															
Norms Committee Decision:																
Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Jun/202425/6 dated 01/07/2024 against advance authorization No.3411004087 dated 08/09/2023, 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:-																
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Clindamycin Phosphate Gel USP 1% - 30 gm tube</td><td>1 Number</td><td>1</td><td>Clindamycin Phosphate USP</td><td>0.306 gm/Tube</td></tr><tr><td>Clindamycin Phosphate Gel USP1%</td><td>1 Number</td><td>2</td><td>Clindamycin Phosphate USP</td><td>0.612 gm/Tube</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Clindamycin Phosphate Gel USP 1% - 30 gm tube	1 Number	1	Clindamycin Phosphate USP	0.306 gm/Tube	Clindamycin Phosphate Gel USP1%	1 Number	2	Clindamycin Phosphate USP	0.612 gm/Tube
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Clindamycin Phosphate Gel USP 1% - 30 gm tube	1 Number	1	Clindamycin Phosphate USP	0.306 gm/Tube												
Clindamycin Phosphate Gel USP1%	1 Number	2	Clindamycin Phosphate USP	0.612 gm/Tube												

- 60 gm tube				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	119 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	ABHILASH LIFE SCIENCES LLP
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00002225AM25
RA File Number	32AX04000268 AM25
Licence No and Date	3211007242/30/07/2024

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.
Moclobemide 150 mg film-coated tablets	1 Number	1	Moclobemide	153 mg./Tablet
Moclobemide 300 mg film-coated tablets	1 Number	2	Moclobemide	306 mg/Tablet

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

Case No.	120 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00003199AM25
RA File Number	03AX04002805 AM25
Licence No and Date	0311037291/20/09/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
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				allowed.
2-CHLORO-7-CYCLOPENTYL-N,N-DIMETHYL-7H-PYRROLO [2,3-d] PYRIMIDINE-6-CARBOXAMIDE (LEE011-B7)	1 kg.	1	5-Bromo-2-Chloro-N-Cyclopentyl Pyrimidine-4-Amine (LEE011-B1)	2.70 kg.
		2	Propargyl Alcohol (LEE011-B2)	1.00 kg.
		3	2,2,6,6-tetramethylpiperidin-1-yl) oxidanyl(TEMPO)	0.200 kg.
		4	Dimethyl Sulfoxide (DMSO)	2.50 kg.
		5	Acetonitrile	3.86 kg.
		6	Toluene	1.00 kg.
		7	2-Methyl Tetrahydrofuran	10.00 kg.
		8	n-HEPTANE	3.10 kg.

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

Case No.	121 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00003488AM25
RA File Number	03AX04003251 AM25
Licence No and Date	0311037662/04/10/2024

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.
VILDAGLIPTIN	1 kg.	1	L-Proline	0.855 kg.
		2	3-Amino-1-Adamantol	0.904 kg.
		3	Methyl Ethyl Ketone	2.07 kg.
		4	Dimethyl Formamide	0.74 kg.
		5	Isopropyl Alcohol	0.97 kg.

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

Case No.	122 / NC/3/MEET/Mar/202425/18
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202425/ 18 and 17/03/2025
HQ File Number	HQRNORM APPLY 00003529AM25
RA File Number	03AX04003242 AM25
Licence No and Date	0311037737/08/10/2024

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.
Phenobarbitone / Phenobarbital	1 kg.	1	Dimethyl Carbonate	0.871 kg.
		2	Sodium Methoxide Powder	0.494 kg.
		3	Sodium Methoxide Solution (30%)	1.319 kg.

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

