



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Jan/202425/15

DATED: 28/01/2025

Please Note

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

Meeting No. NC/3/MEET/Jan/202425/15 dated 28/01/2025 of Norms Committee - III for the year 2024-25 was held on 28/01/2025 under the Chairmanship of Shri Rakesh Kumar, Additional DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2023.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	Shri Rakesh Kumar, Addl. DGFT	DGFT(HQ)
2	Shri Raman Kumar, Deputy DGFT	DGFT(HQ)
3	Shri NAND Lal, Technical Consultant	Consultant (Chemical)
4	Shri SHAISH KUMAR, Technical Consultant	Consultant (Chemical)
5	Shri DINESHNARAIN MATHUR, Technical	Consultant (Pharma)

	Consultant	
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Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00003389AM23
RA File Number	08AX04001054 AM23
Licence No and Date	0811006114/26/09/2022
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:- Certificate of Analysis (CoA) of import item from Foreign Supplier.	

Case No.	2 / NC/3/MEET/Jan/202425/15																				
Case Status	Case Approved																				
Party Name	ALEMBIC PHARMACEUTICALS LIMITED																				
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025																				
HQ File Number	HQRNORM APPLY 00003395AM23																				
RA File Number	34AX04000620 AM23																				
Licence No and Date	3411002830/27/09/2022																				
Norms Committee Decision:																					
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																					
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Cream(Clobetasol Propionate Cream USP 0.05% 15 gm (net content of active ingredients 450.00 gm.))</td><td>60000 Numbers</td><td>1</td><td>Clobetasol Propionate USP (Micronized)</td><td>459.0 gm.</td></tr><tr><td>Cream(Clobetasol Propionate Cream USP 0.05% 30 gm (net content of active ingredients 450.00 gm.))</td><td>30000 Numbers</td><td>2</td><td>Clobetasol Propionate USP (Micronized)</td><td>459.0 gm.</td></tr><tr><td>Cream(Clobetasol Propionate Cream USP</td><td>35000</td><td>3</td><td>Clobetasol Propionate</td><td>803.25 gm.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Cream(Clobetasol Propionate Cream USP 0.05% 15 gm (net content of active ingredients 450.00 gm.))	60000 Numbers	1	Clobetasol Propionate USP (Micronized)	459.0 gm.	Cream(Clobetasol Propionate Cream USP 0.05% 30 gm (net content of active ingredients 450.00 gm.))	30000 Numbers	2	Clobetasol Propionate USP (Micronized)	459.0 gm.	Cream(Clobetasol Propionate Cream USP	35000	3	Clobetasol Propionate	803.25 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																	
Cream(Clobetasol Propionate Cream USP 0.05% 15 gm (net content of active ingredients 450.00 gm.))	60000 Numbers	1	Clobetasol Propionate USP (Micronized)	459.0 gm.																	
Cream(Clobetasol Propionate Cream USP 0.05% 30 gm (net content of active ingredients 450.00 gm.))	30000 Numbers	2	Clobetasol Propionate USP (Micronized)	459.0 gm.																	
Cream(Clobetasol Propionate Cream USP	35000	3	Clobetasol Propionate	803.25 gm.																	

0.05% 45 gm (net content of active ingredients 787.50 gm.))	Numbers		USP (Micronized)	
Cream(Clobetasol Propionate Cream USP 0.05% 60 gm (net content of active ingredients 1200.00 gm.))	40000 Numbers	4	Clobetasol Propionate USP (Micronized)	1224.0 gm.
Solution(Clobetasol Propionate Topical Solution USP 0.05% 25ml (net content of active ingredients 500.00 gm.))	40000 Numbers	5	Clobetasol Propionate USP (Micronized)	510.0 gm.
Solution(Clobetasol Propionate Topical Solution USP 0.05% 50 ml (net content of active ingredients 375.00 gm.))	15000 Numbers	6	Clobetasol Propionate USP (Micronized)	382.50 gm.
Shampoo(Clobetasol Propionate Shampoo, 0.05% 118 ml (net content of active ingredients 2360.00 gm.))	40000 Numbers	7	Clobetasol Propionate USP (Micronized)	2407.2 gm.
Spray(Clobetasol Propionate Spray, 0.05% - 59 ml (net content of active ingredients 295.00 gm.))	10000 Numbers	8	Clobetasol Propionate USP (Micronized)	300.90 gm.
Spray(Clobetasol Propionate Spray, 0.05% - 125 ml (net content of active ingredients 500.00 gm.))	8000 Numbers	9	Clobetasol Propionate USP (Micronized)	510.0 gm.
Ointment(Clobetasol Propionate Ointment USP 0.05% 15 gm (net content of active ingredients 375.00 gm.))	50000 Numbers	10	Clobetasol Propionate USP (Micronized)	382.50 gm.
Ointment(Clobetasol Propionate Ointment USP 0.05% 30 gm (net content of active ingredients 525.00 gm.))	35000 Numbers	11	Clobetasol Propionate USP (Micronized)	535.50 gm.
Ointment(Clobetasol Propionate Ointment USP 0.05% 45 gm (net content of active ingredients 450.00 gm.))	20000 Numbers	12	Clobetasol Propionate USP (Micronized)	459.0 gm.
Ointment(Clobetasol Propionate Ointment USP 0.05% 60 gm (net content of active ingredients 750.00 gm.))	25000 Numbers	13	Clobetasol Propionate USP (Micronized)	765.0 gm.

Foam(Clobetasol Propionate Foam USP 0.05% 50gm. (net content of active ingredients 750.00 gm.))	30000 Numbers	14	Clobetasol Propionate USP (Micronized)	765.0 gm.
Foam(Clobetasol Propionate Foam USP 0.05% 100 gm. (net content of active ingredients 1000.00 gm.))	20000 Numbers	15	Clobetasol Propionate USP (Micronized)	1020.0 gm.

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

Case No.	3 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00003479AM23
RA File Number	08AX04000835 AM23
Licence No and Date	0811006153/30/09/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 200 mcg per 50 mL (4 mcg/mL) NET CONTENTS _12.58GM(Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 200mcg per 50mL (4mcg/mL) NETCONTENTS_12.58GM)	1 Number	1	Dexmedetomidine import under PC 9 CONDITION	210 mg.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 400 mcg per 100 mL (4 mcg/mL) NET CONTENTS _200 GM (Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 400 mcg per 100 mL (4 mcg/mL) NET CONTENTS_ 200 GM)	1 Number	2	Dexmedetomidine import under PC 9 CONDITION	420 mg.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 200 mcg/50 mL (4 mcg/mL) NET CONTENTS_	1 Number	3	Dexmedetomidine import under PC 9	210 mg.

7.20GM(Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 200 mcg/50 mL (4 mcg/mL) NET CONTENTS_ 7.20 GM)			CONDITION	
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 400 mcg/100 mL (4 mcg/mL) NET CONTENTS_5.22 GM(Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 400 mcg/100 mL (4 mcg/mL) NET CONTENTS_ 5.22 GM)	1 Number	4	Dexmedetomidine import under PC 9 CONDITION	420 mg.
Esmolol Hydrochloride in Sodium Chloride Injection 2,500 mg/250 mL (10 mg/mL) NET CONTENTS_70 KGS (Esmolol Hydrochloride in Sodium Chloride Injection 2,500 mg/250 mL (10 mg/mL) NET CONTENTS_70 KGS)	1 Number	5	ESMOLOL Import under PC 9 CONDITION	2625 mg.
Esmolol Hydrochloride in Sodium Chloride Injection [DOUBLE STRENGTH] 2,000 mg/100 mL (20 mg/mL) NET CONTENTS _30 KGS (EsmololHydrochlorideinSodiumChloride Injection[DOUBLESTRENGTH]2,000mg/100mL(20mg/mL)NET CONTENTS_30 KGS)	1 Number	6	ESMOLOL Import under PC 9 CONDITION	2100 mg.
Ropivacaine HCI Injection, USP 0.5% 500 mg/100 mL (5 mg/mL) NET CONTENTS _ 2.55 KGS(Ropivacaine HCI Injection, USP 0.5% 500 mg/100 mL (5 mg/mL) NET CONTENTS_2.55 KGS)	1 Number	7	ROPIVACAINE Import under PC 9 CONDITION	525 mg.
Ropivacaine HCI Injection, USP 0.5% 1,000 mg/200 mL (5 mg/mL) NET CONTENTS_2.315 KGS (Ropivacaine HCI Injection, USP 0.5% 1,000 mg/200 mL (5 mg/mL) NET CONTENTS_2.315 KGS)	1 Number	8	ROPIVACAINE Import under PC 9 CONDITION	1000 mg.
Ropivacaine HCI Injection, USP 0.2% 200 mg/100 mL (2 mg/mL) NET CONTENTS _11.4 KGS (Ropivacaine HCI Injection, USP 0.2% 200 mg/100 mL (2 mg/mL) NET CONTENTS_11.4 KGS)	1 Number	9	ROPIVACAINE Import under PC 9 CONDITION	200 mg.
Ropivacaine HCI Injection, USP 0.2% 400 mg/200 mL (2 mg/mL) NET CONTENTS_19.24 KGS (Ropivacaine HCI Injection, USP 0.2% 400 mg/200 mL (2 mg/mL) NET CONTENTS_19.24 KGS)	1 Number	10	ROPIVACAINE Import under PC 9 CONDITION	420 mg.

Case No.	4 / NC/3/MEET/Jan/202425/15
Case Status	Case Rejected
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00003514AM23
RA File Number	03AX04003421 AM23
Licence No and Date	0311018336/03/10/2022
Norms Committee Decision: The Committee considered the request of the 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 input Galaxmusk Pure (Perfumery Compound) as applied by the firm appears to fall 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. The applicant firm is requested to clarify how this application comes under Para 4.07 of HBP and the RA concerned is directed to provide its comments.	

Case No.	5 / NC/3/MEET/Jan/202425/15										
Case Status	Case Approved										
Party Name	CORAL DRUGS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025										
HQ File Number	HQRNORM APPLY 00003543AM23										
RA File Number	05AX04001818 AM23										
Licence No and Date	0511015160/06/10/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Fluticasone Propionate (EP/BP/USP/IP)</td><td>1 kg.</td><td>1</td><td>8 DM</td><td>1.73 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Fluticasone Propionate (EP/BP/USP/IP)	1 kg.	1	8 DM	1.73 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Fluticasone Propionate (EP/BP/USP/IP)	1 kg.	1	8 DM	1.73 mg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	6 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00003610AM23
RA File Number	34AX04000652 AM23
Licence No and Date	3411002874/10/10/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Midodrine HCL Tabs USP 2.5 mg	1 Number	1	Midodrine Hydrochloride USP (Micronized)	2.55 mg.
		2	Microcrystalline Cellulose (Avicel PH 102)	74.5 mg.
		3	Crospovidone (Type-A) (Polyplasdone) XL	8.00 mg.
		4	Hydroxypropyl cellulose(KLUCEL LF PHARM)	1.50 mg.
		5	Colloidal Silicon dioxide (Aerosil 200 Pharma)	2.00 mg.
		6	Magnesium Stearate	1.50 mg.
Midodrine HCL Tabs USP 5 mg	1 Number	7	Midodrine Hydrochloride USP (Micronized)	5.10 mg.
		8	Microcrystalline Cellulose (Avicel PH 102)	149.0 mg.

		9	Crospovidone (Type-A) (Polyplasdone) XL	16.0 mg.
		10	Hydroxypropyl cellulose(KLUCEL LF PHARM)	3.0 mg.
		11	Colloidal Silicon dioxide (Aerosil 200 Pharma)	4.0 mg.
		12	Magnesium Stearate	3.0 mg.
Midodrine HCL Tabs USP 10 mg	1 Number	13	Midodrine Hydrochloride USP (Micronized)	10.20 mg.
		14	Microcrystalline Cellulose (Avicel PH 102)	298.0 mg.
		15	Crospovidone (Type-A) (Polyplasdone) XL	32.0 mg.
		16	Hydroxypropyl cellulose(KLUCEL LF PHARM)	6.00 mg.
		17	Colloidal Silicon dioxide (Aerosil 200 Pharma)	8.00 mg.
		18	Magnesium Stearate	6.00 mg.

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

Case No.	7 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	LIVEALTH BIOPHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00003619AM23
RA File Number	03AX04003335 AM23

Licence No and Date	0311018491/11/10/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SUCCIMER CAPSULES 100 MG SUXIMER (200 packs of 10 x 10 Capsules)	1 Number	1	SUCCIMER DMSA (2,3-Dimercapto Succinic acid)	100.00 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	8 / NC/3/MEET/Jan/202425/15			
Case Status	Case Approved			
Party Name	ALEMBIC PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025			
HQ File Number	HQRNORM APPLY 00003629AM23			
RA File Number	34AX04000662 AM23			
Licence No and Date	3411002884/11/10/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Guanfacine Extended-Release Tablets USP 1 mg (Net content of active ingredients 3.900 kgs)	1 Number	1	Guanfacine Hydrochloride	1.171 mg.
		2	Methacrylic Acid and Ethyl	55.00 mg.

			Acrylate Copolymer (Eudragit L 100-55)	
		3	Hypromellose (Methocel K15M Premium CR Grade)	55.00 mg.
		4	Microcrystalline Cellulose (Avicel PH 102)	10.00 mg.
		5	Lactose Monohydrate (Flowlac 100)	46.35 mg.
		6	Magnesium stearate	1.00 mg.
Guanfacine Extended-Release Tablets USP 2 mg (Net content of active ingredients 7.800 kgs)	1 Number	7	Guanfacine Hydrochloride	2.342 mg.
		8	Methacrylic Acid and Ethyl Acrylate Copolymer (Eudragit L 100-55)	55.00 mg.
		9	Hypromellose (Methocel K15M Premium CR Grade)	55.00 mg.
		10	Microcrystalline Cellulose (Avicel PH 102)	10.00 mg.
		11	Lactose Monohydrate (Flowlac 100)	45.20 mg.
		12	Magnesium stearate	1.00 mg.
Guanfacine Extended-Release Tablets USP 3 mg (Net content of active ingredients 7.50 kgs)	1 Number	13	Guanfacine Hydrochloride	3.513 mg.
		14	Methacrylic Acid and Ethyl Acrylate Copolymer (Eudragit L 100-55)	55.00 mg.
		15	Hypromellose (Methocel K15M Premium CR Grade)	55.00 mg.
		16	Microcrystalline Cellulose (Avicel PH 102)	10.00 mg.

		17	Lactose Monohydrate (Flowlac 100)	43.56 mg.
		18	Magnesium stearate	1.00 mg.
Guanfacine Extended-Release Tablets USP 4 mg (Net content of active ingredients 9.60 kgs)	1 Number	19	Guanfacine Hydrochloride	4.684 mg.
		20	Methacrylic Acid and Ethyl Acrylate Copolymer (Eudragit L 100-55)	55.00 mg.
		21	Hypromellose (Methocel K15M Premium CR Grade)	55.00 mg.
		22	Microcrystalline Cellulose (Avicel PH 102)	10.00 mg.
		23	Lactose Monohydrate (Flowlac 100)	42.40 mg.
		24	Magnesium stearate	1.00 mg.

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

Case No.	9 / NC/3/MEET/Jan/202425/15
Case Status	Case Rejected
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00003691AM23
RA File Number	09AX04000567 AM23
Licence No and Date	0911003791/13/10/2022
Norms Committee Decision:	
The firm vide letter dated 09/06/2023 has informed that they have surrendered their above license to RA. Therefore, the Committee decided to close the application of the firm.	

Case No.	10 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00003897AM23
RA File Number	07AX04001077 AM23
Licence No and Date	0711005539/21/10/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CALCIUM CITRATE MALATE USP	1 kg.	1	CITRIC ACID-ANY GRADE	0.477 kg.
		2	DL-MALIC ACID	0.499 kg.
		3	CALCIUM CARBONATE	0.712 kg.

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

Case No.	11 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00003925AM23
RA File Number	09AX04000647 AM23
Licence No and Date	0911003881/27/10/2022

Norms Committee Decision:

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

product/import item in meeting **No.NC/3/MEET/Dec/202425/13** dated **07/01/2025** against advance authorization **No.0911003541** dated **26/08/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2butyl16dihydro- NN,4trimethyl6oxo1[[2[1(triphenylmethyl)- 1H-tetrazol-5- yl][1,1biphenyl]4yl)methyl]5- Pyrimidineacetamide (Drug Intermediate)	1 kg.	1	Chloroform	1.90 kg.
		2	Toluene	2.06 kg.
		3	5-(4-(Bromomethyl)biphenyl-2-yl)-2-trityl-2H-Tetrazole (N-(Triphenylmethyl)	1.02 kg.
		4	Dimethyl Sulfoxide	0.46 kg.
		5	Lithium hydride	0.0166 kg.

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

Case No.	12 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	NECTAR LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00003987AM23
RA File Number	302404000100 AM20
Licence No and Date	3011002766/01/11/2022
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	13 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM REVIW00006136AM24
RA File Number	52AX04001711 AM23
Licence No and Date	5211003710/07/12/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents from the firm: To indicate stepwise yield of the reaction and whether the overall yield of the reaction is 67.18% as shown and accordingly, to calculate the requirement of raw materials. Justification of low yield of the reaction giving the details of losses during the process and the value of by-product/s of the reaction generated during the process. Current production/consumption data duly certified by Chartered Accountant.	

Case No.	14 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM REVIW00006412AM24
RA File Number	09AX04000649 AM23
Licence No and Date	0911004131/08/12/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with other relevant cases.	

Case No.	15 / NC/3/MEET/Jan/202425/15
Case Status	Case Rejected
Party Name	VINYL PRODUCTS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM REVIW00001983AM25
RA File Number	05AX04002721 AM23
Licence No and Date	0511016406/15/12/2022
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo. The exports and imports under this are also similar to SION A-1303 therefore the committee also decided to review the SION A-1303.	

Case No.	16 / NC/3/MEET/Jan/202425/15
Case Status	Case Rejected
Party Name	LYRUS LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000961AM24
RA File Number	NA
Licence No and Date	0711006229/19/01/2023
Norms Committee Decision: The Committee considered the request of the firm and observed that the firm has filed dual application on same license, therefore, the committee has decided to close the application of the firm.	

Case No.	17 / NC/3/MEET/Jan/202425/15
Case Status	Case Rejected
Party Name	MICROTROL STERILISATION SERVICES PVT.LTD.
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00005834AM23
RA File Number	07AX04001525 AM23
Licence No and Date	0711006236/19/01/2023
Norms Committee Decision: The Committee considered the case as per the agenda and the firm has informed during personal hearing that they have surrendered the license to concerned RA. Therefore, the Committee has decided to close the	

application of the firm.

Case No.	18 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00005935AM23
RA File Number	03AX04005248 AM23
Licence No and Date	0311020993/27/01/2023

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/202324/16 dated 17/11/2023** against advance authorization **No.0311024614 dated 16/06/2023**, 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.
Fenofibrate 145mg tablets) (6,78,60,000Nos) (NetContent:1) 9955.062KGS2) 9878.380KGS3) (Indi):2004.584KGS 4) (Indi):196.115KGS 5) (Indi):681.993KGS 6) (Indi):8864.552KGS 7) (Indi):5778.279KGS 8) (Indi):5067.785KGS 9) (Indi):61.074KGS 10) (Indi): 2015.442KGS)	1 kg.	1	Fenofibrate Micronized IH/Ph Eur	147.90 mg.
		2	Sucrose PH.Eur (exepient)	143.575 mg.

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

Case No.	19 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00005968AM23
RA File Number	03AX04005323 AM23
Licence No and Date	0311021042/30/01/2023

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/Sep/202425/9 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.	20 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved

Party Name	KRITI NUTRIENTS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025										
HQ File Number	HQRNORM REVIW00001038AM25										
RA File Number	56AX04000363 AM23										
Licence No and Date	5611001525/02/02/2023										
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Sep/202425/9 dated 10/10/2024 against advance authorization No.5611000556 dated 12/10/2021, 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 border="1" data-bbox="197 793 1431 1088"> <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>Soya Lecithin Liquid Food Grade (Non GMO)</td><td>1 kg.</td><td>1</td><td>Soya Lecithin Liquid</td><td>1.00 kg.</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Soya Lecithin Liquid Food Grade (Non GMO)	1 kg.	1	Soya Lecithin Liquid	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Soya Lecithin Liquid Food Grade (Non GMO)	1 kg.	1	Soya Lecithin Liquid	1.00 kg.							

Case No.	21 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00006103AM23
RA File Number	05AX04003187 AM23
Licence No and Date	0511017188/06/02/2023
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Amoxycillin Trihydrate and Clavulanate Potassium + Silicon Dioxide (1:1) Suspension 156.25mg/5ml (100ml Bottle, Each 5 ml contains Amoxycillin Trihydrate equivalent to Amoxycillin 125mg &Clavulanate Potassium + Silicon Dioxide (1:1) equivalent to Clavulanic acid 31.25mg) (Equivalent to 95.000Kg of Amoxycillin Trihydrate &23.750Kg of Clavulan	38000 Numbers	1	Amoxycillin Trihydrate	99.75 kg.
		2	Clavulanate Potassium + Silicon Dioxide (1:1)	58.92 kg.
Amoxycillin Trihydrate and Clavulanate Potassium + Silicon Dioxide (1:1) Suspension 228.50mg/5ml (70ml Bottle, Each 5 ml contains Amoxycillin Trihydrate equivalent to Amoxycillin 200mg &Clavulanate Potassium + Silicon Dioxide (1:1) equivalent to Clavulanic acid 28.5mg) (Equivalent to 78.400Kg of Amoxycillin Trihydrate &11.172Kg of Clavulanate	28000 Numbers	3	Amoxycillin Trihydrate	82.32 kg.
		4	Clavulanate Potassium + Silicon Dioxide (1:1)	27.72 kg.
Amoxycillin Trihydrate and Clavulanate Potassium + Silicon Dioxide (1:1) Suspension 312.5mg/5ml 60ml Bottle, Each 5 ml contains Amoxycillin Trihydrate equivalent to Amoxycillin 250mg &Clavulanate Potassium + Silicon Dioxide (1:1) equivalent to Clavulanic acid 62.5mg) (Equivalent to 84.000Kg of Amoxycillin Trihydrate &21.000Kg of Clavulanat	28000 Numbers	5	Amoxycillin Trihydrate	88.2 kg.
		6	Clavulanate Potassium + Silicon Dioxide (1:1)	52.1 kg.
Amoxycillin Trihydrate and Clavulanate Potassium + Silicon Dioxide (1:1) Suspension 457.00mg/5ml (70ml Bottle, Each 5 ml contains Amoxycillin Trihydrate equivalent to Amoxycillin 400mg &Clavulanate Potassium + Silicon Dioxide (1:1) equivalent to Clavulanic acid 57mg) (Equivalent to 156.800Kg of Amoxycillin Trihydrate & 22.344Kg of Clavulanate	28000 Numbers	7	Amoxycillin Trihydrate	164.64 kg.
		8	Clavulanate Potassium + Silicon Dioxide (1:1)	55.44 kg.

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

Case No.	22 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00006153AM23
RA File Number	34AX04001000 AM23
Licence No and Date	3411003357/07/02/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cream(Clobetasol Propionate Cream USP 0.05% 15 gm (net content of active ingredients 525.00 gm.))	70000 Numbers	1	Clobetasol Propionate USP (Micronized)	535.5 gm.
Cream(Clobetasol Propionate Cream USP 0.05% 30 gm (net content of active ingredients 600.00 gm.))	40000 Numbers	2	Clobetasol Propionate USP (Micronized)	612.0 gm.
Cream(Clobetasol Propionate Cream USP 0.05% 45 gm (net content of active ingredients 1012.50 gm.))	45000 Numbers	3	Clobetasol Propionate USP (Micronized)	1032.75 gm.
Cream(Clobetasol Propionate Cream USP 0.05% 60 gm (net content of active ingredients 1800.00 gm.))	60000 Numbers	4	Clobetasol Propionate USP (Micronized)	1836.0 gm.
Solution(Clobetasol Propionate Topical Solution USP 0.05% 25ml (net content of active ingredients 625.00 gm.))	50000 Numbers	5	Clobetasol Propionate USP (Micronized)	637.5 gm.
Solution(Clobetasol Propionate Topical Solution USP 0.05% 50 ml (net content of active ingredients 500.00 gm.))	20000 Numbers	6	Clobetasol Propionate USP (Micronized)	510.0 gm.

Shampoo(Clobetasol Propionate Shampoo, 0.05% 118 ml (net content of active ingredients 2950.00 gm.))	50000 Numbers	7	Clobetasol Propionate USP (Micronized)	3009.0 gm.
Spray(Clobetasol Propionate Spray, 0.05% - 59 ml (net content of active ingredients 442.50 gm.))	15000 Numbers	8	Clobetasol Propionate USP (Micronized)	451.35 gm.
Spray(Clobetasol Propionate Spray, 0.05% - 125 ml (net content of active ingredients 625.00 gm.))	10000 Numbers	9	Clobetasol Propionate USP (Micronized)	637.50 gm.
Ointment(Clobetasol Propionate Ointment USP 0.05% 15 gm (net content of active ingredients 450.00 gm.))	60000 Numbers	10	Clobetasol Propionate USP (Micronized)	459.0 gm.
Ointment(Clobetasol Propionate Ointment USP 0.05% 30 gm (net content of active ingredients 675.00 gm.))	45000 Numbers	11	Clobetasol Propionate USP (Micronized)	688.50 gm.
Ointment(Clobetasol Propionate Ointment USP 0.05% 45 gm (net content of active ingredients 675.00 gm.))	30000 Numbers	12	Clobetasol Propionate USP (Micronized)	688.50 gm.
Ointment(Clobetasol Propionate Ointment USP 0.05% 60 gm (net content of active ingredients 1800.00 gm.))	60000 Numbers	13	Clobetasol Propionate USP (Micronized)	1836.0 gm.
Foam(Clobetasol Propionate Foam USP 0.05% 50gm. (net content of active ingredients 1000.00 gm.))	40000 Numbers	14	Clobetasol Propionate USP (Micronized)	1020.0 gm.
Foam(Clobetasol Propionate Foam USP 0.05% 100 gm. (net content of active ingredients 1500.00 gm.))	30000 Numbers	15	Clobetasol Propionate USP (Micronized)	1530.0 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	23 / NC/3/MEET/Jan/202425/15
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Case Status	Case Approved													
Party Name	ALTA LABORATORIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025													
HQ File Number	HQRNORM APPLY 00006165AM23													
RA File Number	03AX04005445 AM23													
Licence No and Date	0311021243/08/02/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202324/25 dated 11/03/2024 against advance authorization No.0311029142 dated 06/12/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">PROPYL PARABEN</td><td rowspan="2">1 kg.</td><td>1</td><td>PARAHYDROXY BENZOIC ACID</td><td>0.80 kg.</td></tr><tr><td>2</td><td>N PROPANOL</td><td>0.347 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PROPYL PARABEN	1 kg.	1	PARAHYDROXY BENZOIC ACID	0.80 kg.	2	N PROPANOL	0.347 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
PROPYL PARABEN	1 kg.	1	PARAHYDROXY BENZOIC ACID	0.80 kg.										
		2	N PROPANOL	0.347 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	24 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00006212AM23
RA File Number	34AX04001024 AM23
Licence No and Date	3411003367/09/02/2023
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ORTHO NITRO TOLUENE	1 kg.	1	NITRIC ACID 68%	0.675 kg.
		2	TOLUENE	0.661 kg.
		3	SULPHURIC ACID 98%	Deleted procured from Indigenous source
		4	SODA ASH	Deleted procured from Indigenous source

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

Case No.	25 / NC/3/MEET/Jan/202425/15																
Case Status	Case Approved																
Party Name	GLENMARK PHARMACEUTICALS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025																
HQ File Number	HQRNORM APPLY 00006186AM23																
RA File Number	03AX04005398 AM23																
Licence No and Date	0311021275/09/02/2023																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Clindamycin & Benzoyl Peroxide Gel 1%/5% (Pack Size 25gm) ((Net Wt. of Import Item Sr. No. 1 is 8.75 Kgs. &Sr. No. 2 is 43.75 Kgs.))</td><td rowspan="2">1 Number Pack</td><td>1</td><td>Clindamycin Phosphate USP</td><td>262.50 mg/pack</td></tr><tr><td>2</td><td>HYDROUS BENZOYL PEROXIDE USP</td><td>1312.50 mg/pack</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Clindamycin & Benzoyl Peroxide Gel 1%/5% (Pack Size 25gm) ((Net Wt. of Import Item Sr. No. 1 is 8.75 Kgs. &Sr. No. 2 is 43.75 Kgs.))	1 Number Pack	1	Clindamycin Phosphate USP	262.50 mg/pack	2	HYDROUS BENZOYL PEROXIDE USP	1312.50 mg/pack
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Clindamycin & Benzoyl Peroxide Gel 1%/5% (Pack Size 25gm) ((Net Wt. of Import Item Sr. No. 1 is 8.75 Kgs. &Sr. No. 2 is 43.75 Kgs.))	1 Number Pack	1	Clindamycin Phosphate USP	262.50 mg/pack													
		2	HYDROUS BENZOYL PEROXIDE USP	1312.50 mg/pack													

Clindamycin & Benzoyl Peroxide Gel 1%/5% (Pack Size 35gm) ((Net Wt. of Import Item Sr. No. 1 is 17.50 Kgs. & Sr. No. 2 is 87.50 Kgs.))	1 Number Pack	3	HYDROUS BENZOYL PEROXIDE USP	367.50 mg/pack
		4	Clindamycin Phosphate USP	1837.50 mg/pack
Clindamycin & Benzoyl Peroxide Gel 1%/5% (Pack Size 50gm)((Net Wt. of Import Item Sr. No. 1 is 17.50 Kgs. & Sr. No. 2 is 87.50 Kgs.))	1 Number Pack	5	Clindamycin Phosphate USP	525.00 mg/pack
		6	HYDROUS BENZOYL PEROXIDE USP	2625.00 mg/pack
CLINDAMYCIN PHOSPHATE GEL 1% (Pack Size 30gm) (Net Wt. of Import Item Sr. No. 2 is 10.50 Kgs.)	1 Number Pack	7	Clindamycin Phosphate USP	306.00 mg/pack
CLINDAMYCIN PHOSPHATE GEL 1% (Pack Size 60gm) (Net Wt. of Import Item Sr. No. 2 is 210.00 Kgs.)	1 Number Pack	8	Clindamycin Phosphate USP	612.00 mg/pack
Adapalene & Benzoyl Peroxide Gel 0.1%/2.5% (Pack Size 45gm) (Net Wt. of Import Item Sr. No. 2 is 112.50 Kgs.)	1 Number Pack	9	HYDROUS BENZOYL PEROXIDE USP	1181.25 mg/pack
RA concerned may take further necessary action as per above decision of NC.				

Case No.	26 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025

and Date	
HQ File Number	HQRNORM APPLY 00006267AM23
RA File Number	09AX04000893 AM23
Licence No and Date	0911004453/13/02/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Dec/202424/25 dated 07/01/2025** against advance authorization **No.0911003340 dated 13/07/2022**, 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.
Valaciclovir HCl	1 kg.	1	Guanine	0.80 kg.
		2	Dioxolane Diacetate	1.30 kg.
		3	Acetone	0.69 kg.
		4	Aqueous Dimethyl Amine	1.64 kg.
		5	Acetic Acid	0.47 kg.
		6	CBZ - L - Valine	1.112 kg.
		7	N,N-Dicyclohexyl carbodimide	1.14 kg.
		8	Dimethylaminopyridine	0.028 kg.
		9	Dimethyl formamide	1.92 kg.
		10	methanol	4.82 kg.
		11	Isopropanol	2.55 kg.

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

Case No.	27 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ARCH PROTECTION CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00007396AM24
RA File Number	NA
Licence No and Date	0311021465/15/02/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Jan/202324/21 dated 24/01/2024** against advance authorization **No.0311021465 dated 15/02/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BIT 84 PERCENTAGE 400KG BB IN 1-2 Benzisothiazoline-3-One and Various Pack sizes (25 Kg, 250 Kg and 400Kg etc.) import (Net Content in export product as follows Sr No 1 and 2 with qty 0.98 Kg, & Mtr 2.525 Kg per Kg.)	1 kg.	1	2- CHLOROBENZ ONITRILE	0.968 kg.
		2	SODIUM METHYL MERCAPTIDE 20%	2.418 kg.

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

Case No.	28 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025

and Date														
HQ File Number	HQRNORM APPLY 00006441AM23													
RA File Number	03AX04005543 AM23													
Licence No and Date	0311021564/20/02/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202424/25 dated 07/01/2025 against advance authorization No.0311035363 dated 10/07/2024 , 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Fenofibrate 48mg tablets</td><td rowspan="2">1 Number</td><td>1</td><td>Fenofibrate Micronized IH/Ph Eur</td><td>48.96 mg.</td></tr><tr><td>2</td><td>Sucrose PH.Eur (exepient)</td><td>145.57 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Fenofibrate 48mg tablets	1 Number	1	Fenofibrate Micronized IH/Ph Eur	48.96 mg.	2	Sucrose PH.Eur (exepient)	145.57 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Fenofibrate 48mg tablets	1 Number	1	Fenofibrate Micronized IH/Ph Eur	48.96 mg.										
		2	Sucrose PH.Eur (exepient)	145.57 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	29 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00006594AM23
RA File Number	30AX04000547 AM23
Licence No and Date	3011003202/24/02/2023
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:- Advance Authorisation shows 4 inputs whereas in Annexure to Appendix-4E, only 3 inputs are shown. Please give justification and whether 4th item (Ethyl Acetate) is to be deleted from import. In case Ethyl Acetate is required, furnish complete chemistry, molecular weight and percentage	

yield on molar basis.

3. Requirement and recovery of solvent at each step.

4. Material balance for each step.

5. Production/Conduction data for the last three years duly certified by Chartered Accountant.

Case No.	30 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	MAHARASHTRA ALDEHYDES AND CHEMICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00006735AM23
RA File Number	03AX04004601 AM23
Licence No and Date	0311021876/03/03/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it has been observed the firm has not furnished the complete reply of DL as sought by the Committee during the meeting held on 08.06.2023. Hence it was decided to call for following information/documents from the firm:- 1. Step wise manufacturing process. 2. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. 3. Complete technical details as per Annexure to Appendix-4E for chemical products. 4. Stoichiometric balance between import and export on molar basis. 5. Details of indigenous input with quantity.	

Case No.	31 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	AARTI PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00006751AM23
RA File Number	03AX04005685 AM23
Licence No and Date	0311021895/04/03/2023
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DI ETHYL SULPHATE	1 kg.	1	ETHANOL	0.746 kg.
		2	SO3	1.29 kg.
		3	SODIUM SULPHATE	0.114 kg.
		4	UREA	0.19 kg.

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

Case No.	32 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00006767AM23
RA File Number	07AX04001781 AM23
Licence No and Date	0711006639/06/03/2023

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 showing net content of import item no.2.**
- 2. Justification for quantity of packing material with samples.**

Case No.	33 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved

Party Name	ZYDUS LIFESCIENCES LIMITED																																											
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025																																											
HQ File Number	HQRNORM APPLY 00006898AM23																																											
RA File Number	08AX04002105 AM23																																											
Licence No and Date	0811007519/10/03/2023																																											
Norms Committee Decision:																																												
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																																												
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="8">CHLORPROMAZINE HYDROCHLORIDE TABLETS USP 10 MG((ACTIVE INGREDIENT: CHLORPROMAZINE HYDROCHLORIDE USP - 37.482 KGS))</td><td rowspan="8">1 Number</td><td>1</td><td>CHLORPROMAZINE HYDROCHLORIDE USP</td><td>10.2 mg</td></tr><tr><td>2</td><td>LACTOSE MONOHYDRATE NF/PH.E</td><td>5.57 mg.</td></tr><tr><td>3</td><td>MICROCRYSTALLINE CELLULOSE NF/IP/PH.E/BP (AVICEL PH102)</td><td>36.0 mg.</td></tr><tr><td>4</td><td>CALCIUM SULPHATE DIHYDRATE NF</td><td>3.60 mg.</td></tr><tr><td>5</td><td>SODIUM STARCH GLYCOLATE NF/JP</td><td>2.43 mg.</td></tr><tr><td>6</td><td>CROSCARMELLOSE SODIUM NF</td><td>2.71 mg.</td></tr><tr><td>7</td><td>MAGNESIUM STEARATE PH.E/NF/JP</td><td>1.00 mg.</td></tr><tr><td>8</td><td>METHYL ALCOHOL NF</td><td>24.49 mg.</td></tr><tr><td rowspan="2">CHLORPROMAZINE HYDROCHLORIDE TABLETS USP 25 MG((ACTIVE INGREDIENT: CHLORPROMAZINE HYDROCHLORIDE USP - 104.965 KGS))</td><td rowspan="2">1 Number</td><td>9</td><td>CHLORPROMAZINE HYDROCHLORIDE USP</td><td>25.50 mg.</td></tr><tr><td>10</td><td>LACTOSE MONOHYDRATE</td><td>13.925 mg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CHLORPROMAZINE HYDROCHLORIDE TABLETS USP 10 MG((ACTIVE INGREDIENT: CHLORPROMAZINE HYDROCHLORIDE USP - 37.482 KGS))	1 Number	1	CHLORPROMAZINE HYDROCHLORIDE USP	10.2 mg	2	LACTOSE MONOHYDRATE NF/PH.E	5.57 mg.	3	MICROCRYSTALLINE CELLULOSE NF/IP/PH.E/BP (AVICEL PH102)	36.0 mg.	4	CALCIUM SULPHATE DIHYDRATE NF	3.60 mg.	5	SODIUM STARCH GLYCOLATE NF/JP	2.43 mg.	6	CROSCARMELLOSE SODIUM NF	2.71 mg.	7	MAGNESIUM STEARATE PH.E/NF/JP	1.00 mg.	8	METHYL ALCOHOL NF	24.49 mg.	CHLORPROMAZINE HYDROCHLORIDE TABLETS USP 25 MG((ACTIVE INGREDIENT: CHLORPROMAZINE HYDROCHLORIDE USP - 104.965 KGS))	1 Number	9	CHLORPROMAZINE HYDROCHLORIDE USP	25.50 mg.	10	LACTOSE MONOHYDRATE	13.925 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																																								
CHLORPROMAZINE HYDROCHLORIDE TABLETS USP 10 MG((ACTIVE INGREDIENT: CHLORPROMAZINE HYDROCHLORIDE USP - 37.482 KGS))	1 Number	1	CHLORPROMAZINE HYDROCHLORIDE USP	10.2 mg																																								
		2	LACTOSE MONOHYDRATE NF/PH.E	5.57 mg.																																								
		3	MICROCRYSTALLINE CELLULOSE NF/IP/PH.E/BP (AVICEL PH102)	36.0 mg.																																								
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		7	MAGNESIUM STEARATE PH.E/NF/JP	1.00 mg.																																								
		8	METHYL ALCOHOL NF	24.49 mg.																																								
CHLORPROMAZINE HYDROCHLORIDE TABLETS USP 25 MG((ACTIVE INGREDIENT: CHLORPROMAZINE HYDROCHLORIDE USP - 104.965 KGS))	1 Number	9	CHLORPROMAZINE HYDROCHLORIDE USP	25.50 mg.																																								
		10	LACTOSE MONOHYDRATE	13.925 mg.																																								

			NF/PH.E	
		11	MICROCRYSTALLINE CELLULOSE NF/IP/PH.E/BP (AVICEL PH102)	29.67 mg.
		12	CALCIUM SULPHATE DIHYDRATE NF	11.175 mg.
		13	SODIUM STARCH GLYCOLATE NF/JP	6.075 mg.
		14	CROSCARMELLOSE SODIUM NF	6.775 mg.
		15	MAGNESIUM STEARATE PH.E/NF/JP	1.40 mg.
		16	METHYL ALCOHOL NF	61.22 mg.
CHLORPROMAZINE HYDROCHLORIDE TABLETS USP 50 MG((ACTIVE INGREDIENT: CHLORPROMAZINE HYDROCHLORIDE USP - 479.890 KGS))	1 Number	17	CHLORPROMAZINE HYDROCHLORIDE USP	51.00 mg.
		18	LACTOSE MONOHYDRATE NF/PH.E	18.30 mg.
		19	MICROCRYSTALLINE CELLULOSE NF/IP/PH.E/BP (AVICEL PH102)	38.95 mg.
		20	CALCIUM SULPHATE DIHYDRATE NF	18.75 mg.
		21	SODIUM STARCH GLYCOLATE NF/JP	10.50 mg.
		22	CROSCARMELLOSE SODIUM NF	10.50 mg.
		23	MAGNESIUM STEARATE PH.E/NF/JP	2.25 mg.

		24	METHYL ALCOHOL NF	122.45 mg.
CHLORPROMAZINE HYDROCHLORIDE TABLETS USP 100 MG((ACTIVE INGREDIENT: CHLORPROMAZINE HYDROCHLORIDE USP - 519.880 KGS))	1 Number	25	CHLORPROMAZINE HYDROCHLORIDE USP	102.00 mg.
		26	LACTOSE MONOHYDRATE NF/PH.E	36.60 mg.
		27	MICROCRYSTALLINE CELLULOSE NF/IP/PH.E/BP (AVICEL PH102)	77.90 mg.
		28	CALCIUM SULPHATE DIHYDRATE NF	37.50 mg.
		29	SODIUM STARCH GLYCOLATE NF/JP	21.00 mg.
		30	CROSCARMELLOSE SODIUM NF	21.00 mg.
		31	MAGNESIUM STEARATE PH.E/NF/JP	4.50 mg.
		32	METHYL ALCOHOL NF	244.90 mg.
CHLORPROMAZINE HYDROCHLORIDE TABLETS USP 200 MG((ACTIVE INGREDIENT: CHLORPROMAZINE HYDROCHLORIDE USP - 799.600 KGS))	1 Number	33	CHLORPROMAZINE HYDROCHLORIDE USP	204.00 mg.
		34	LACTOSE MONOHYDRATE NF/PH.E	73.20 mg.
		35	MICROCRYSTALLINE CELLULOSE NF/IP/PH.E/BP (AVICEL PH102)	155.80 mg.
		36	CALCIUM SULPHATE DIHYDRATE NF	75.00 mg.
		37	SODIUM STARCH GLYCOLATE NF/JP	42.00 mg.

		38	CROSCARMELLOSE SODIUM NF	42.00 mg.
		39	MAGNESIUM STEARATE PH.E/NF/JP	9.00 mg.
		40	METHYL ALCOHOL NF	489.8 mg.

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

Case No.	34 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM REVIW00006563AM24
RA File Number	08AX04001977 AM23
Licence No and Date	0811007532/10/03/2023
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. Balance Chemical reaction between Aniline and formaldehyde and accordingly calculations of the requirement of Aniline based on 100% yield, as mentioned. 2. Composition of Formulated Aromatic Amine, indicating three components of Basic Amine. 3. The commercial value of By-product/s during reaction and indigenous item/s used in the process	

Case No.	35 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	MAHIMA LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00006908AM23

RA File Number	05AX04003427 AM23													
Licence No and Date	0511017696/10/03/2023													
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/202424/2 dated 30/04/2024 against advance authorization No.0311021914 dated 06/03/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table 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>DEFLAZACORT</td><td>1 kg.</td><td>1</td><td>11B, 16 B) 11-HYDROXY - 2 - METHYL - 5 H- PREGNA- 1,4- DIENO (17, 16-D) OXAZOLE - 3, 20- DIONE (D5)</td><td>1.00 kg.</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DEFLAZACORT	1 kg.	1	11B, 16 B) 11-HYDROXY - 2 - METHYL - 5 H- PREGNA- 1,4- DIENO (17, 16-D) OXAZOLE - 3, 20- DIONE (D5)	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
DEFLAZACORT	1 kg.	1	11B, 16 B) 11-HYDROXY - 2 - METHYL - 5 H- PREGNA- 1,4- DIENO (17, 16-D) OXAZOLE - 3, 20- DIONE (D5)	1.00 kg.										

Case No.	36 / NC/3/MEET/Jan/202425/15								
Case Status	Case Approved								
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025								
HQ File Number	HQRNORM APPLY 00006981AM23								
RA File Number	03AX04006011 AM23								
Licence No and Date	0311022155/15/03/2023								
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/202424/2 dated 30/04/2024 against advance authorization No.0311024276 dated 06/06/2023, 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> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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.	37 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025

HQ File Number	HQRNORM APPLY 00007009AM23															
RA File Number	30AX04000578 AM23															
Licence No and Date	3011003279/16/03/2023															
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <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>VINOELBINE SOLUTION FOR INJECTION (50MG/5ML) (1 ML OF SOLUTION CONTAINS: VINOELBINE TARTRATE , EQUIVALENT TO VINOELBINE 10 MG EXCIPIENTS: TARTARIC ACID, WATER FOR INJECTION)</td><td>1 Number</td><td>1</td><td>VINOELBINE TARTRATE</td><td>69.00 mg.</td></tr> <tr> <td>VINOELBINE SOLUTION FOR INJECTION (10MG/ML) (1 ML OF SOLUTION CONTAINS: VINOELBINE TARTRATE , EQUIVALENT TO VINOELBINE 10 MG EXCIPIENTS: TARTARIC ACID, WATER FOR INJECTION)</td><td>1 Number</td><td>2</td><td>VINOELBINE TARTRATE</td><td>13.80 mg.</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	VINOELBINE SOLUTION FOR INJECTION (50MG/5ML) (1 ML OF SOLUTION CONTAINS: VINOELBINE TARTRATE , EQUIVALENT TO VINOELBINE 10 MG EXCIPIENTS: TARTARIC ACID, WATER FOR INJECTION)	1 Number	1	VINOELBINE TARTRATE	69.00 mg.	VINOELBINE SOLUTION FOR INJECTION (10MG/ML) (1 ML OF SOLUTION CONTAINS: VINOELBINE TARTRATE , EQUIVALENT TO VINOELBINE 10 MG EXCIPIENTS: TARTARIC ACID, WATER FOR INJECTION)	1 Number	2	VINOELBINE TARTRATE	13.80 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
VINOELBINE SOLUTION FOR INJECTION (50MG/5ML) (1 ML OF SOLUTION CONTAINS: VINOELBINE TARTRATE , EQUIVALENT TO VINOELBINE 10 MG EXCIPIENTS: TARTARIC ACID, WATER FOR INJECTION)	1 Number	1	VINOELBINE TARTRATE	69.00 mg.												
VINOELBINE SOLUTION FOR INJECTION (10MG/ML) (1 ML OF SOLUTION CONTAINS: VINOELBINE TARTRATE , EQUIVALENT TO VINOELBINE 10 MG EXCIPIENTS: TARTARIC ACID, WATER FOR INJECTION)	1 Number	2	VINOELBINE TARTRATE	13.80 mg.												

Case No.	38 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00007011AM23
RA File Number	07AX04001891 AM23
Licence No and Date	0711006773/16/03/2023
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Calcium Dobesilate Monohydrate BP/ Calcium Dobesilate Monohydrate Eur.Ph / Calcium Dobesilate(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.	39 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM REVIW00006561AM24
RA File Number	04AX04001126 AM23
Licence No and Date	0411005084/21/03/2023

Norms Committee Decision:

Decision: The Committee considered the request of firm for a review of ad-hoc norms and on the basis of information provided by the firm, it was decided to check from RA about the change in the description of items in the Authorisation. The case is deferred for the next meeting.

Case No.	40 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025																
HQ File Number	HQRNORM APPLY 00007173AM23																
RA File Number	31AX04000352 AM23																
Licence No and Date	3111002109/24/03/2023																
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/Sep/202424/9 dated 10/10/2024 against advance authorization No.3111001838 dated 24/11/2022, 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:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 86.66% W/W WHITE GRANULES POWDER</td> <td rowspan="2">1 kg.</td> <td>1</td> <td>DICYANDIAMIDE (DCDA) WHITE POWDER</td> <td>0.484 kg.</td> </tr> <tr> <td>2</td> <td>SODIUM STARCH GLYCOLATE WHITE POWDER</td> <td>0.034 kg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 86.66% W/W WHITE GRANULES POWDER	1 kg.	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.484 kg.	2	SODIUM STARCH GLYCOLATE WHITE POWDER	0.034 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 86.66% W/W WHITE GRANULES POWDER	1 kg.	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.484 kg.													
		2	SODIUM STARCH GLYCOLATE WHITE POWDER	0.034 kg.													

Case No.	41 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	VINS BIOPRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
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 cases as per the agenda. The representatives of the firm attended the	

Personal Hearing through Video Conference wherein Technical Expert of the Department of Bio-Technology was also present through VC. The representative of the firm explained the reason for the enhancement of ad-hoc norms in respect of the above Advance Authorisations as well as other AA No. 0910066851 dated 14/11/2018, No. 0910068189 dated 15/11/2019 & No. 0911003795 dated 13/10/2022 for same export/import items.

The Committee heard the explanation of the firm and after due deliberation with the Technical Expert of Deptt. of Bio-Technology decided to enhance the wastage norms to 5%. Accordingly, DBT will send their comments on above said applications.

Case No.	42 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000059AM24
RA File Number	03AX04006327 AM23
Licence No and Date	0311022677/10/04/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Diazepam Rectal Gel 2.5mg/ 0.5 ml and Lubricating Jelly (Combo Pack) ((Each Pack having 2.5mg twin pack with 2 packets of 3gm lubricating jelly (Net Wt. of Diazepam USP is 150.00 Grams))	1 Number Combo Pack	1	Diazepam USP	0.0051 gm.
Diazepam Rectal Gel 10 mg/ 2 ml and Lubricating Jelly (Combo Pack) ((Each Pack having 10 mg Delivery system twin pack with 2 packets of 3gm lubricating jelly) (Net Wt. of Diazepam USP is	1 Number Combo Pack	2	Diazepam USP	0.0204 gm.

2000.00 Grams))				
Diazepam Rectal Gel 20 mg/ 4 ml and Lubricating Jelly (Combo Pack) ((Each Pack having 20 mg Delivery system twin pack with 2 packets of 3gm lubricating jelly) (Net Wt. of Diazepam USP is 2000.00 Grams))	1 Number Combo Pack	3	Diazepam USP	0.0408 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	43 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000075AM24
RA File Number	08AX04002209 AM23
Licence No and Date	0811007825/10/04/2023

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/202324/16 dated 17/11/2023** against advance authorization **No.0811002393 dated 25/08/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 1ML VIAL(EACH ML CONTAINS: VINORELBINE TARTRATE PH.EUR EQ. TO VINORELBINE 10 MG)	1 Number	1	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR (Water content 2.3%)	14.33 mg.
VINORELBINE CONCENTRATE	1 Number	2	VINORELBINE	71.66 mg.

FOR SOLUTION FOR INFUSION 10MG/ML, 5ML VIAL(EACH ML CONTAINS:VINOELBINE TARTRATE PH.EUR EQ. TO VINOELBINE 10 MG [IN WHICH ACTIVE INGREDIENT VINOELBINE TARTRATE USED IS 606.000 GRAMS])			TARTRATE EP / BP / IP / USP / PH. EUR (Water content 2.3%)	
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RA concerned may take further necessary action as per above decision of NC.

Case No.	44 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	LITMUS ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000097AM24
RA File Number	03AX04006355 AM23
Licence No and Date	0311022717/11/04/2023
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-	

Case No.	45 / NC/3/MEET/Jan/202425/15													
Case Status	Case Approved													
Party Name	GENERIC HEALTHCARE PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025													
HQ File Number	HQRNORM APPLY 00000102AM24													
RA File Number	31AX04000374 AM23													
Licence No and Date	3111002194/11/04/2023													
Norms Committee Decision:														
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>MEQUI-GH 2,5MG/5ML SP F/60ML</td><td>76058 Numbers</td><td>1</td><td>Mequitazine</td><td>2.3 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MEQUI-GH 2,5MG/5ML SP F/60ML	76058 Numbers	1	Mequitazine	2.3 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
MEQUI-GH 2,5MG/5ML SP F/60ML	76058 Numbers	1	Mequitazine	2.3 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	46 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000136AM24
RA File Number	03AX04006098 AM23
Licence No and Date	0311022771/12/04/2023
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.0511023876 dated 09/02/2024 , 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 Items	Qty. allowed.
2- ACETOACETOXY ETHYL METHACRYLATE	1 kg.	1	Acetic Acid	0.755 kg.
		2	2-Hydroxyethyl Methacrylate	0.640 kg.

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

Case No.	47 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000156AM24
RA File Number	08AX04000016 AM24
Licence No and Date	0811007856/12/04/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. 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 108.347 Kg in export item)	1 Number	1	Nystatin (Nystatin Micronized)	245.586 mg/ Tablet
Nystatin Cream USP, 100000 units/gm,	1 Number	2	Nystatin (Nystatin	491.172 mg/

30gm (30gm Tube)(Each gram Contains: 100,000 USP Nystatin Units in anaqueous, cream base. Net content of Nystatin should not be less than 231.140 Kg in export item)			Micronized)	Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	48 / NC/3/MEET/Jan/202425/15			
Case Status	Case Approved			
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025			
HQ File Number	HQRNORM APPLY 00000159AM24			
RA File Number	03AX04000117 AM24			
Licence No and Date	0311022786/13/04/2023			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-				

Case No.	49 / NC/3/MEET/Jan/202425/15
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Case Status	Case Deferred
Party Name	S KANT CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000218AM24
RA File Number	03AX04000033 AM24
Licence No and Date	0311022832/17/04/2023
Norms Committee Decision: The committee considered the request of firm for review/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:- Complete technical details as per Annexure to Appendix-4E.	

Case No.	50 / NC/3/MEET/Jan/202425/15																			
Case Status	Case Approved																			
Party Name	MOREPEN LABORATORIES LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025																			
HQ File Number	HQRNORM APPLY 00000238AM24																			
RA File Number	05AX04000110 AM24																			
Licence No and Date	0511018340/17/04/2023																			
Norms Committee Decision:																				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-																				
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="3">ATORVASTATIN CALCIUM</td><td rowspan="3">1 kg.</td><td>1</td><td>(4R-Cis)-1,1-Dimethylethyl-6-cyanomethyl-2,2-dimethyl-1,3-dioxane - 4-Acetate</td><td>0.6259 kg.</td></tr><tr><td>2</td><td>4-Fluoro-α-[2-methyl-1-oxopropyl]-γ-oxo-N-β-diphenyl benzene butanamide</td><td>0.994 kg.</td></tr><tr><td>3</td><td>Methanol</td><td>4.285 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ATORVASTATIN CALCIUM	1 kg.	1	(4R-Cis)-1,1-Dimethylethyl-6-cyanomethyl-2,2-dimethyl-1,3-dioxane - 4-Acetate	0.6259 kg.	2	4-Fluoro- α -[2-methyl-1-oxopropyl]- γ -oxo-N- β -diphenyl benzene butanamide	0.994 kg.	3	Methanol	4.285 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
ATORVASTATIN CALCIUM	1 kg.	1	(4R-Cis)-1,1-Dimethylethyl-6-cyanomethyl-2,2-dimethyl-1,3-dioxane - 4-Acetate	0.6259 kg.																
		2	4-Fluoro- α -[2-methyl-1-oxopropyl]- γ -oxo-N- β -diphenyl benzene butanamide	0.994 kg.																
		3	Methanol	4.285 kg.																

		4	Methyl tert-butyl ether (M201)	1.145 kg.
		5	Tetrahydrofuran	0.542 kg.
		6	Methylene chloride	1.414 kg.
		7	Diisopropyl ether	0.754 kg.

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

Case No.	51 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000266AM24
RA File Number	08AX04002260 AM23
Licence No and Date	0811007905/18/04/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SPIRONOLACTONE TABLETS USP 25 MG ((ACTIVE INGREDIENT: SPIRONOLACTONE USP - NET WT. 6982.100 KGS))	1 Number	1	SPIRONOLACTONE USP	25.50 mg.
		2	CORN STARCH NF	17.50 mg.
		3	CROSCARMELLOSE SODIUM NF	9.00 mg.
		4	POVIDONE USP	7.50 mg.

			(K-29/32)	
		5	MICROCRYSTALLINE CELLULOSE NF 102	4.50 mg.
		6	MAGNESIUM STEARATE PH EUR/NF	1.125 mg.
		7	CALCIUM SULPHATE DIHYDRATE NF	86.375 mg.
SPIRONOLACTONE TABLETS USP 50 MG(ACTIVE INGREDIENT: SPIRONOLACTONE USP - NET WT. 7717.200 KGS))	1 Number	8	SPIRONOLACTONE USP	51.00 mg.
		9	CORN STARCH NF	35.00 mg.
		10	CROSCARMELLOSE SODIUM NF	18.00 mg.
		11	POVIDONE USP (K-29/32)	15.00 mg.
		12	MICROCRYSTALLINE CELLULOSE NF 102	9.00 mg.
		13	MAGNESIUM STEARATE PH EUR/NF	2.25 mg.
		14	CALCIUM SULPHATE DIHYDRATE NF	172.75 mg.
SPIRONOLACTONE TABLETS USP 100 MG (ACTIVE INGREDIENT: SPIRONOLACTONE USP - NET WT.8189.400 KGS))	1 Number	15	SPIRONOLACTONE USP	102.00 mg.
		16	CORN STARCH NF	70.00 mg.
		17	CROSCARMELLOSE SODIUM NF	36.00 mg.
		18	POVIDONE USP (K-29/32)	30.00 mg.
		19	MICROCRYSTALLINE CELLULOSE NF 102	18.00 mg.

		20	MAGNESIUM STEARATE PH EUR/NF	4.50 mg.
		21	CALCIUM SULPHATE DIHYDRATE NF	345.50 mg.

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

Case No.	52 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000292AM24
RA File Number	03AX04000045 AM24
Licence No and Date	0311022935/19/04/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	53 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000325AM24
RA File Number	03AX04000169 AM24
Licence No and Date	0311022998/21/04/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	54 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000357AM24
RA File Number	03AX04000234 AM24
Licence No and Date	0311023026/24/04/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Olopatadine Hydrochloride and Mometasone Furoate Nasal Spray 600mcg/25mcg (RYALTRIS) 240 MD((Net Wt. of Mometasone Furoate mono. is 4200 Grams))	700000 Numbers	1	Mometasone Furoate Monohydrate	4284.00 gm.
Olopatadine Hydrochloride and Mometasone Furoate Nasal Spray 600mcg/25mcg (RYALTRIS) 240 MD((Net Wt. of Mometasone Furoate mono. is 2100 Grams))	350000 Numbers	2	Mometasone Furoate Monohydrate	2142.00 gm.
Olopatadine Hydrochloride and Mometasone Furoate Nasal Spray 600mcg/25mcg (RYALTRIS) 120 MD((Net Wt. of Mometasone Furoate mono. is 2100 Grams))	700000 Numbers	3	Mometasone Furoate Monohydrate	2142.00 gm.
Olopatadine Hydrochloride and Mometasone Furoate Nasal Spray 600mcg/25mcg (RYALTRIS) 120 MD((Net Wt of Mometasone Furoate mono. is 1050 Grams))	350000 Numbers	4	Mometasone Furoate Monohydrate	1071.00 gm.
Olopatadine Hydrochloride and Mometasone Furoate Nasal Spray	400000 Numbers	5	Mometasone Furoate Monohydrate	571.20 gm.

600mcg/25mcg (RYALTRIS) 56 MD((Net Wt.of Mometasone Furoate mono. is 560 Grams))				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	55 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	IND SWIFT LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000384AM24
RA File Number	30AX04000022 AM24
Licence No and Date	3011003465/25/04/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Clarithromycin Granules 27.5% (Suspension Grade)	1 kg.	1	Clarithromycin	0.2727 kg.
		2	Carbopol	0.2000 kg.
		3	HPMC Phthalate	0.5400 kg.
		4	Acetate	1.0500 kg.

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

Case No.	56 / NC/3/MEET/Jan/202425/15										
Case Status	Case Approved										
Party Name	SENTISS PHARMA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025										
HQ File Number	HQRNORM APPLY 00000404AM24										
RA File Number	05AX04000234 AM24										
Licence No and Date	0511018526/25/04/2023										
Norms Committee Decision:											
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Kombinil-DUO Eye/Ear Drops 5ml Vial (Each ml contains 1 mg. of Dexamethasone)</td><td>1 Number</td><td>1</td><td>Dexamethasone Micronised PH EUR USP JP</td><td>5.10 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Kombinil-DUO Eye/Ear Drops 5ml Vial (Each ml contains 1 mg. of Dexamethasone)	1 Number	1	Dexamethasone Micronised PH EUR USP JP	5.10 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Kombinil-DUO Eye/Ear Drops 5ml Vial (Each ml contains 1 mg. of Dexamethasone)	1 Number	1	Dexamethasone Micronised PH EUR USP JP	5.10 mg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	57 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	ALKALOIDS PVT LTD.
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000398AM24
RA File Number	02AX04000047 AM24
Licence No and Date	0211004284/25/04/2023
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:-	

Certificate of Analysis (CoA) of import item from Foreign Supplier showing percentage content of active ingredient.

Case No.	58 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000425AM24
RA File Number	34AX04000059 AM24
Licence No and Date	3411003627/26/04/2023

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/Jun/202425/5 dated 14/06/2024** against advance authorization **No.3411001598 dated 28/12/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. 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 (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.	59 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved

Party Name	NASENSE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000429AM24
RA File Number	09AX04000054 AM24
Licence No and Date	0911004884/26/04/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4 Dimethyl Aminopyridine	1 kg.	1	4-Cyanopyridine	1.0 kg.
		2	Cp HCl (33 percent)	1.14 kg.
		3	Acrylic Acid	0.70 kg.
		4	Dimethylamine 40 percent Solution	1.5 kg.
		5	Caustic Soda Flakes	1.15 kg.
		6	Toluene	0.2 kg.

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

Case No.	60 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000446AM24
RA File Number	07AX04000091 AM24
Licence No and	0711007425/27/04/2023

Date				
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.
CALCIUM CITRATE MALATE USP	1 kg.	1	CITRIC ACID ANY GRADE	0.477 kg.
		2	DL-MALIC ACID	0.499 kg.
		3	CALCIUM CARBONATE	0.712 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	61 / NC/3/MEET/Jan/202425/15			
Case Status	Case Approved			
Party Name	ALEMBIC PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025			
HQ File Number	HQRNORM APPLY 00000488AM24			
RA File Number	34AX04000058 AM24			
Licence No and Date	3411003648/29/04/2023			
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/Dec/202425/13 dated 07/01/2025 against advance authorization No.3411002610 dated 04/08/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Midodrine HCL Tabs USP 2.5 mg	1 Number	1	Midodrine Hydrochloride USP (Micronized)	2.55 mg.
		2	Microcrystalline Cellulose (Avicel PH 102)	74.50 mg.
		3	Crospovidone (Type-A) (Polyplasdone) XL	8.00 mg.
		4	Hydroxypropyl cellulose (KLUCEL LF PHARM)	1.50 mg.
		5	Colloidal Silicon dioxide (Aerosil 200 Pharma)	2.00 mg.
		6	Magnesium Stearate	1.50 mg.
Midodrine HCL Tabs USP 5 mg	1 Number	7	Midodrine Hydrochloride USP (Micronized)	5.10 mg.
		8	Microcrystalline Cellulose (Avicel PH 102)	149.00 mg.
		9	Crospovidone (Type-A) (Polyplasdone) XL	16.00 mg.
		10	Hydroxypropyl cellulose (KLUCEL LF PHARM)	3.00 mg.
		11	Colloidal Silicon dioxide (Aerosil 200 Pharma)	4.00 mg.
		12	Magnesium Stearate	3.00 mg.
Midodrine HCL Tabs USP 10 mg	1 Number	13	Midodrine Hydrochloride USP (Micronized)	10.20 mg.

		14	Microcrystalline Cellulose (Avicel PH 102)	298.00 mg.
		15	Crospovidone (Type-A) (Polyplasdone) XL	32.00 mg.
		16	Hydroxypropyl cellulose (KLUCEL LF PHARM)	6.00 mg.
		17	Colloidal Silicon dioxide (Aerosil 200 Pharma)	8.00 mg.
		18	Magnesium Stearate	6.00 mg.

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

Case No.	62 / NC/3/MEET/Jan/202425/15			
Case Status	Case Approved			
Party Name	HUMAN PHARMA LABS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025			
HQ File Number	HQRNORM APPLY 00000508AM24			
RA File Number	08AX04000018 AM24			
Licence No and Date	0811008029/01/05/2023			
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.0311031505 dated 27/02/2024 , 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:-				

DEXAMETHASONE	1 kg.	1	16 Alpha-Methyl Epoxide (8-DM)	0.811 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	63 / NC/3/MEET/Jan/202425/15			
Case Status	Case Approved			
Party Name	AVIK PHARMACEUTICAL LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025			
HQ File Number	HQRNORM APPLY 00000541AM24			
RA File Number	52AX04000022 AM24			
Licence No and Date	5211004680/03/05/2023			
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:-				

Case No.	64 / NC/3/MEET/Jan/202425/15			
Case Status	Case Approved			
Party Name	ZYDUS LIFESCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025			
HQ File Number	HQRNORM APPLY 00000547AM24			
RA File Number	08AX04000159 AM24			
Licence No and Date	0811008069/03/05/2023			

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.
PYRIDOSTIGMINE BROMIDE TABLETS USP 60 MG (ACTIVE INGREDIENT)	1Number	1	PYRIDOSTIGMINE BROMIDE USP	61.20 mg.
		2	ANHYDROUS LACTOSE NF/BP	297.37 mg.

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

Case No.	65 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	CLAROID PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000559AM24
RA File Number	08AX04000122 AM24
Licence No and Date	0811008065/03/05/2023

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.
ERYTHROMYCIN 500 MG (1,42,00,000 TABLETS) (ERYTHROMYCIN STEARATE 706 MG IS EQUILENT TO	1 Number	1	ERYTHROMYCIN STEARATE	668 mg/Tablet

ERYTHROMYCIN 500 MG)

Note: The committee decided to recommend for revision of SION A-334.

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

Case No.	66 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ALKEM LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000683AM24
RA File Number	03AX04000499 AM24
Licence No and Date	0311023438/09/05/2023

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.
Venlafaxine Hydrochloride Extended Release Tablets 37.5 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 37.5mg. Net content of Venlafaxine 15.374 kgs)	409980 Numbers	1	Venlafaxine Hydrochloride USP	17.68 kg.
Venlafaxine Hydrochloride Extended Release Tablets 150 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 150 mg. Net content of Venlafaxine 270 kgs)	1800000 Numbers	2	Venlafaxine Hydrochloride USP	299.7 kg.

Venlafaxine Hydrochloride Extended Release Tablets 75 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 75 mg. Net content of Venlafaxine 63 kgs)	840000 Numbers	3	Venlafaxine Hydrochloride USP	70.56 kg.
Venlafaxine Hydrochloride Extended Release Tablets 37.5 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 37.5mg. Net content of Venlafaxine 4.687 kgs)	125010 Numbers	4	Venlafaxine Hydrochloride USP	5.39 kg.
Venlafaxine Hydrochloride Extended Release Tablets 150 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 150 mg. Net content of Venlafaxine 247.500 kgs)	1650000 Numbers	5	Venlafaxine Hydrochloride USP	274.725 kg.
Venlafaxine Hydrochloride Extended Release Tablets 225 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 225mg. Net content of Venlafaxine 85.500 kgs)	380010 Numbers	6	Venlafaxine Hydrochloride USP	94.052 kg.
Venlafaxine Hydrochloride Extended Release Tablets 37.5 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 37.5mg. Net content of Venlafaxine 3.375kgs)	90000 Numbers	7	Venlafaxine Hydrochloride USP	3.881 kg.
Venlafaxine Hydrochloride Extended Release Tablets 75 mg(Each extended release tablet contains:	180000 Numbers	8	Venlafaxine Hydrochloride USP	15.12 kg.

Venlafaxine Hydrochloride equivalent to venlafaxine 75 mg. Net content of Venlafaxine 13.5 kgs)				
Venlafaxine Hydrochloride Extended Release Tablets 150 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 150 mg. Net content of Venlafaxine 24.745 kgs)	164970 Numbers	9	Venlafaxine Hydrochloride USP	27.466 kg.
Venlafaxine Hydrochloride Extended Release Tablets 225 mg(Each extended release tablet contains: Venlafaxine Hydrochloride equivalent to venlafaxine 225mg. Net content of Venlafaxine 42.747 kgs)	189990 Numbers	10	Venlafaxine Hydrochloride USP	47.021 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	67 / NC/3/MEET/Jan/202425/15			
Case Status	Case Approved			
Party Name	BLUE JET HEALTHCARE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025			
HQ File Number	HQRNORM APPLY 00000740AM24			
RA File Number	03AX04000488 AM24			
Licence No and Date	0311023468/10/05/2023			
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:-				

5-Amino -N,N-bis (2,3 - dihydroxypropyl)-2,4,6 -triiodo 1,3-benzenedicarboxamide	1 kg.	1	ISOPHTHALIC ACID	0.350 kg.
		2	3-AMINO-1,2-PROPANEDIOL (APD)	0.320 kg.
		3	EPICHLOROHYDRIN	Not required
		4	PALLADIUM CARBON	0.0001 kg.
		5	METHANOL	2.00 kg.
		6	IODINE	0.50 kg.

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

Case No.	68 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000743AM24
RA File Number	08AX04000207 AM24
Licence No and Date	0811008136/10/05/2023

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/202324/1 dated 28/04/2023** against advance authorization **No.0811006808 dated 21/12/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ASPIRIN TABLETS 75 MG(EACH UNCOATED TABLET CONTAINS	1 Number	1	ASPIRIN (ACETYL SALICYLIC ACID) EP / BP /	76.5 mg.

ACETYL SALICYLIC ACID EP 75 MG)			IP / USP / PH. EUR.	
ASPIRIN ENTERIC COATED TABLETS 81 MG "ECOTRIN 81"(EACH ENTERIC COATED TABLET CONTAINS ASPIRIN BP 81 MG [IN WHICH ACTIVE INGREDIENT ASPIRIN (ACETYL SALICYLIC ACID) USED IS 1240.500 KGS.]	1 Number	2	ASPIRIN (ACETYL SALICYLIC ACID) EP / BP / IP / USP / PH. EUR.	82.62 mg.

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

Case No.	69 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	MEONE HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000746AM24
RA File Number	04AX04000118 AM24
Licence No and Date	0411005383/10/05/2023

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.
FOSCARNET SODIUM INJECTION-250 ML	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.	70 / NC/3/MEET/Jan/202425/15																
Case Status	Case Approved																
Party Name	MEDREICH LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025																
HQ File Number	HQRNORM APPLY 00000768AM24																
RA File Number	07AX04000187 AM24																
Licence No and Date	0711007535/11/05/2023																
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.0711005482 dated 19/10/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Atorvastatin Tablets 10mg</td><td rowspan="2">1 Number</td><td>1</td><td>ATORVASTATIN CALCIUM TRIHYDRATE</td><td>11.059 mg.</td></tr><tr><td>2</td><td>D MANNITOL</td><td>40.0 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Atorvastatin Tablets 10mg	1 Number	1	ATORVASTATIN CALCIUM TRIHYDRATE	11.059 mg.	2	D MANNITOL	40.0 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Atorvastatin Tablets 10mg	1 Number	1	ATORVASTATIN CALCIUM TRIHYDRATE	11.059 mg.													
		2	D MANNITOL	40.0 mg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	71 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	SATYADEVA PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000775AM24
RA File Number	09AX04000090 AM24
Licence No and Date	0911005025/11/05/2023
Norms Committee Decision:	

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

Case No.	72 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000842AM24
RA File Number	08AX04000116 AM24
Licence No and Date	0811008184/15/05/2023

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.
Lapox ARD-13 (Glycidyl ether of fatty alcohol)	1 kg.	1	Palmerol 1214 Lauryl-Myristyl Alcohol Ecorol - 24 Lauryl-Myristyl Alcohol Fatty Alcohol C1214	0.72 kg.
		2	Epichlorohydrin	0.454 kg.

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

Case No.	73 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000850AM24
RA File Number	34AX04000113 AM24

Licence No and Date	3411003716/15/05/2023
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:- Copy of Master-Batch Formula for each export item showing net content of all inputs in the formulations.	

Case No.	74 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	SARAL CHEMTECH LLP
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000865AM24
RA File Number	33AX04000105 AM23
Licence No and Date	3311001206/16/05/2023
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with following information / documents from the firm: 1. Drug Manufacturing License (DML) for each export. 2. Import list is confusing. Give justification for each import item. 3. Production/consumption data for last three years duly certified by Chartered Accountant.	

Case No.	75 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	MAXCURE NUTRAVEDICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000872AM24
RA File Number	05AX04000388 AM24
Licence No and Date	0511018844/16/05/2023
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.0811011244 dated 08/04/2024**, 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.
PIPERACILLIN AND TAZOBACTUM FOR INJECTION 4.5gm (EACH VIAL CONTAINS PIPERACILLIN SODIUM EQUIVALENT TO 4 GM PIPERACILLIN AND TAZOBACTUM SODIUM EQUIVALENT TO 0.5 GM TAZOBACTUM))	1 Number Vial	1	Piperacillin Sodium and Tazobactum Sodium (8:1) Sterile Powder	4.80 gm/vial

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

Case No.	76 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000876AM24
RA File Number	08AX04000284 AM24
Licence No and Date	0811008214/16/05/2023

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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CLOZAPINE TABLETS 25 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 25 MG)	1 Number	1	CLOZAPINE EP / BP / IP / USP / PH. EUR.	25.50 mg/Tablet
CLOZAPINE TABLETS 50 MG(EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 50 MG)	1 Number	2	CLOZAPINE EP / BP / IP / USP / PH. EUR.	51.00 mg/Tablet
CLOZAPINE TABLETS 100 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 100 MG)	1 Number	3	CLOZAPINE EP / BP / IP / USP / PH. EUR.	102.00 mg/Tablet
CLOZAPINE TABLETS 200 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 200 MG [IN WHICH ACTIVE INGREDIENT CLOZAPINE USED IS 96.500 KGS.]	1 Number	4	CLOZAPINE EP / BP / IP / USP / PH. EUR.	204.00 mg/Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	77 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000897AM24
RA File Number	05AX04000410 AM24
Licence No and Date	0511018871/17/05/2023

Norms Committee Decision:

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

Case No.	78 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000920AM24
RA File Number	08AX04000086 AM24
Licence No and Date	0811008233/18/05/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	79 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00000950AM24
RA File Number	09AX04000137 AM24
Licence No and Date	0911005059/18/05/2023
Norms Committee Decision:	
The committee considered the request of firm for review/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:- To give chemical reaction indicating molecular weight of both reactants and products and yield with justification. To give Stoichiometric material balance of the reaction and the value of the by-product/s, if any. Production of export item vis-à-vis consumption of all the raw materials for the last three years duly certified by the Chartered Accountant.	

Case No.	80 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001008AM24
RA File Number	03AX04000694 AM24
Licence No and Date	0311023767/22/05/2023

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.
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 50ml vial((Net content of exempted material is 447.20 kgs) (10000 NOS))	1 Number	1	PROPYLENE GLYCOL	39.52 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 100ml vial((Net content of exempted material is 1252.16 kgs) (14000 NOS))	1 Number	2	PROPYLENE GLYCOL	79.04 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 250ml vial((Net content of exempted material is 603.72 kgs) (2700 NOS))	1 Number	3	PROPYLENE GLYCOL	197.60 gm/Vial
Ashoxy 5% (Oxytetracycline Hydrochloride Injection 50mg) 500ml vial((Net content of exempted material is 894.40 kgs) (2000 NOS))	1 Number	4	PROPYLENE GLYCOL	395.20 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 50ml vial((Net content of exempted material is 426.40 kgs) (10000 NOS))	1 Number	5	PROPYLENE GLYCOL	35.256 gm/Vial

Ashoxy 10% (Oxytetracycline Injection 100mg) 100ml vial((Net content of exempted material is 1705.60 kgs) (20000 NOS))	1 Number	6	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 10% (Oxytetracycline Injection 100mg) 250ml vial((Net content of exempted material is 1066.00 kgs) (5000 NOS))	1 Number	7	PROPYLENE GLYCOL	176.28 gm/Vial
PAN Ashoxy 3% (Oxytetracycline Injection 30mg) 100ml vial((Net content of exempted material is 852.80 kgs) (10000 NOS))	1 Number	8	PROPYLENE GLYCOL	70.512 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 50ml vial((Net content of exempted material is 93.60 kgs) (10000 NOS))	1 Number	9	PROPYLENE GLYCOL	9.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 100ml vial((Net content of exempted material is 187.20 kgs) (10000 NOS))	1 Number	10	PROPYLENE GLYCOL	18.00 gm/Vial
Ashoxy 20% LA (Oxytetracycline Dihydrate Injection eq Oxytetracycline 200mg) 250ml vial((Net content of exempted material is 468.00 kgs) (10000 NOS))	1 Number	11	PROPYLENE GLYCOL	45.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 10ml vial((Net content of exempted material is 101.92 kgs) (10000 NOS))	1 Number	12	PROPYLENE GLYCOL	10.40 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 50ml vial((Net content of exempted material is 509.60 kgs) (10000 NOS))	1 Number	13	PROPYLENE GLYCOL	52.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 100ml vial((Net content of exempted material is 2038.40 kgs) (20000 NOS))	1 Number	14	PROPYLENE GLYCOL	104.00 gm/Vial

Ashiver 1% (Ivermectin 10 Mg Injection) 250ml vial((Net content of exempted material is 1274.00 kgs) (5000 NOS))	1 Number	15	PROPYLENE GLYCOL	260.00 gm/Vial
Ashiver 1% (Ivermectin 10 Mg Injection) 500ml vial((Net content of exempted material is 1017.12 kgs) (2000 NOS))	1 Number	16	PROPYLENE GLYCOL	520.00 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 50ml vial((Net content of exempted material is 512.72 kgs) (10000 NOS))	1 Number	17	PROPYLENE GLYCOL	50.96 gm/Vial
Ashiver Forte (Ivermectin 10mg and Clorsulon 100mg Injection) 100ml vial((Net content of exempted material is 1029.60 kgs) (10000 NOS))	1 Number	18	PROPYLENE GLYCOL	101.92 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 50ml vial((Net content of exempted material is 52.00 kgs) (10000 NOS))	1 Number	19	PROPYLENE GLYCOL	5.20 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 100ml vial((Net content of exempted material is 104.00 kgs) (10000 NOS))	1 Number	20	PROPYLENE GLYCOL	10.40 gm/Vial
Ashienro 10% (Enrofloxacin Injection 100mg) 250ml vial((Net content of exempted material is 260.00 kgs) (10000 NOS))	1 Number	21	PROPYLENE GLYCOL	26.00 gm/Vial
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial((Net content of exempted material is 104.00 kgs) (10000 NOS))	1 Number	22	PROPYLENE GLYCOL	Not matching with Master-Batch Formula
Ashityl 20% (Tylosin Tartrate injection eq to Tylosin 200mg) 100ml vial((Net content of exempted material is 208.00 kgs) (10000 NOS))	1 Number	23	PROPYLENE GLYCOL	20.80 gm/Vial
Ashityl 20% (Tylosin Tartrate injection	1 Number	24	PROPYLENE GLYCOL	Not matching with

eq to Tylosin 200mg) 100ml vial((Net content of exempted material is 520.00 kgs) (10000 NOS))				Master-Batch Formula
Ashityl 5% (Tylosin Tartrate injection eq to Tylosin 50mg) 50ml vial((Net content of exempted material is 104.00 kgs) (10000 NOS))	1 Number	25	PROPYLENE GLYCOL	10.40 gm/Vial
Ashital 10% (Closantel 10% Inj) 100ml vial((Net content of exempted material is 551.20 kgs) (10000 NOS))	1 Number	26	PROPYLENE GLYCOL	55.12 gm/Vial

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

Case No.	81 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001048AM24
RA File Number	08AX04000163 AM24
Licence No and Date	0811008261/23/05/2023

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.
QUETIAPINE TABLETS 25 MG(EACH FILM COATED TABLET CONTAINS: QUETIAPINE FUMARATE PH. EUR. EQ. TO QUETIAPINE 25 MG)	40200000 Numbers	1	QUETIAPINE FUMARATE EP / BP / IP / USP / PH. EUR.	1055.351 kg.

QUETIAPINE PROLONGED RELEASE TABLETS 50 MG(EACH FILM COATED PROLONGED RELEASE TABLET CONTAINS: QUETIAPINE FUMARATE PH.EUR. EQ. TO QUETIAPINE 50 MG)	27000000 Numbers	2	QUETIAPINE FUMARATE EP / BP / IP / USP / PH. EUR.	1397.52 kg.
QUETIAPINE TABLETS 100 MG(EACH FILM COATED TABLET CONTAINS: QUETIAPINE FUMARATE EQ. TO QUETIAPINE 100 MG)	12000000 Numbers	3	QUETIAPINE FUMARATE EP / BP / IP / USP / PH. EUR.	1253.88 kg.
QUETIAPINE PROLONGED RELEASE TABLETS 150 MG(EACH FILM COATED PROLONGED RELEASE TABLET CONTAINS: QUETIAPINE FUMARATE PH. EUR. EQ. TO QUETIAPINE 150 MG)	7200000 Numbers	4	QUETIAPINE FUMARATE EP / BP / IP / USP / PH. EUR.	1137.024 kg.
QUETIAPINE PROLONGED RELEASE TABLETS 200 MG (EACH FILM COATED PROLONGED RELEASE TABLET CONTAINS: QUETIAPINE FUMARATE PH. EUR. EQ. TO QUETIAPINE 200 MG)	4800000 Numbers	5	QUETIAPINE FUMARATE EP / BP / IP / USP / PH. EUR.	993.984 kg.
QUETIAPINE PROLONGED RELEASE TABLETS 300 MG(EACH FILM COATED PROLONGED RELEASE TABLET CONTAINS: QUETIAPINE FUMARATE PH. EUR. EQ. TO QUETIAPINE 300 MG)	3000000 Numbers	6	QUETIAPINE FUMARATE EP / BP / IP / USP / PH. EUR.	918.09 kg.
QUETIAPINE PROLONGED RELEASE TABLETS 400 MG (EACH FILM COATED PROLONGED RELEASE TABLET CONTAINS: QUETIAPINE FUMARATE PH.EUR. EQ. TO QUETIAPINE 400MG [IN WHICH ACTIVE INGREDIENT QUETIAPINE FUMARATE USED	900000 Numbers	7	QUETIAPINE FUMARATE EP / BP / IP / USP / PH. EUR.	374.76 kg.

IS 6855.000 KGS.])				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	82 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	HINDYS LAB PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001037AM24
RA File Number	09AX04001157 AM23
Licence No and Date	0911005091/23/05/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	83 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	AGRO SOLVENT PRODUCTS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001107AM24
RA File Number	56AX04000449 AM23
Licence No and Date	5611001909/25/05/2023
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. Certificate of Analysis (CoA) of import item from foreign supplier. 2. Manufacturing process for each export item. 3. Justification for 84% wastage for export item no. 3. 4. Complete chemistry and molecular weight for export item no.3.	

Case No.	84 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	AARTI PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001158AM24
RA File Number	03AX04000849 AM24
Licence No and Date	0311024010/29/05/2023

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.
DI ETHYL SULPHATE	1 kg.	1	ETHANOL	0.746 kg.
		2	SO3	1.29 kg.
		3	SODIUM SULPHATE	0.114 kg.
		4	UREA	0.19 kg.

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

Case No.	85 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	UNITED MUD-CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001185AM24
RA File Number	03AX04000897 AM24
Licence No and Date	0311024056/30/05/2023

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.
RHEOLOGY MODIFIER	200 MT	1	Dimer Acid	164.96 MT

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

Case No.	86 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001225AM24
RA File Number	30AX04000609 AM23
Licence No and Date	3011003608/31/05/2023

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/Dec/202324/17 dated 20/12/2023** against advance authorization **No.3011002599 dated 19/09/2022**, 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.
Injection Urokinase	1000 Vials	1	Urokinase	1043.46 mg.
		2	Mannitol 0.5%	128.52 gm.
		3	Sodium Chloride (50 mg/vial)	128.52 gm.
		4	Sodium Hydroxide	3.06 gm.

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

Case No.	87 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001205AM24
RA File Number	03AX04000864 AM24
Licence No and Date	0311024068/31/05/2023

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, it was decided to fix ad-hoc norms as under:-

Sl. No	Export Product	Quantity
1	Medical cream, ointment, gel(Betamethasone Dipropionate Cream USP 0.05% 151 gm tube(Wt 2352.96 Kgs Net cont: Sodiumpho7.06Kgs, polyoxyl42.35Kgs, ceto169.41Kgs, petrolatum 352.94kgs ,Minoil 141.18Kgs, Prevantol 2.35Kgs, Propylene 117.65Kgs,Betameth1.65kgs, Tubes 156864 Nos))	1 Number
2	Medical cream, ointment, gel(Betamethasone Dipropionate Cream USP 0.05% 451 gm tube (Wt 2352.92 Kgs Net cont: Sodiumpho 7.06Kgs, polyoxyl 42.35Kgs, ceto 169.41Kgs, petrolatum 352.94kgs, Minoil 141.17Kgs, Prevantol 2.35Kgs, Propylene 117.65Kgs, Betameth1.65kgs, Tubes 52287 Nos))	1 Number
3	Medical cream, ointment, gel(Betamethasone Dipropionate Ointment USP 0.05% 15 Gm (Wt 2941.16 Kgs Net cont: Petrolatum 2909.98 kgs, Min oil 29.41Kgs, Betameth 1.76Kgs, kgs, Tubes 196077 Nos))	1 Number
4	Medical cream, ointment, gel(Betamethasone Dipropionate Ointment USP 0.05% 45 Gm (Wt 2941.11 Kgs Net cont: Petrolatum 2909.93kgs, Min oil 29.41Kgs, Betameth 1.76 Kgs, kgs, Tubes 65358 Nos))	1 Number
5	Name: Medical cream, ointment, gel(Betamethasone Dipropionate USP Ointment Aug 0.05% 15 Gm tube (Wt 589.50 Kgs Netcont: Petrolatum 483.04	1 Number

	kgs, White Wax 35.37 Kgs, Propylene Glycol 11.79 Kgs, Propylene USP 58.95Kgs Betameth 0.35kgs, Tubes 39300 Nos))	
6	Medical cream, ointment, gel(Betamethasone Dipropionate USP Ointment Aug 0.05% 45 Gm tube (Wt 589.50 Kgs Netcont : Petrolatum 483.04kgs, WhiteWax35.37Kgs, PropyleneGlycol11.79Kgs, Propylene USP58.95Kgs Betameth0.35kgs, Tubes13100 Nos))	1 Number

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

Note:

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

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

Case No.	88 / NC/3/MEET/Jan/202425/15
Case Status	Case Rejected
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001246AM24
RA File Number	09AX04000952 AM23
Licence No and Date	0911005147/01/06/2023
Norms Committee Decision:	
The firm vide letter dated 01/06/2023 has informed that they have surrendered their above license to RA.	

Therefore, the Committee decided to **close** the application of the firm.

Case No.	89 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	SHREE GANESH REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001244AM24
RA File Number	34AX04000140 AM24
Licence No and Date	3411003769/01/06/2023
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it has been observed the firm has not furnished the complete reply of DL as sought by the Committee during the meeting held on 30/04/2024. Hence it was decided to call for following information/documents from the firm:- 1. Percentage yield at every stage of reaction. 2. Stichometric balance between import and export to arrive at the norms applied for.	

Case No.	90 / NC/3/MEET/Jan/202425/15	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025	
HQ File Number	HQRNORM APPLY 00001233AM24	
RA File Number	03AX04000925 AM24	
Licence No and Date	0311024109/01/06/2023	
Norms Committee Decision:		
The Committee considered the request of firm in details and also discussed report of factory visit. The committee found that in the above mention case export product is in form of Gel not a cream/Ointments and accordingly decided to fix the ad-hoc norms as under :-		
Sl.	Export Product	Quantity

No		
(i)	CLOTRIMAZOLE OINTMENT 1 % 20G Tot Wt: 7440 kgs (Net Cont: Clotri 79.35Kgs, Cetomacro 171.86Kgs, Ceto 559.49Kgs)(Medicinal Cream / Ointments)	1 Number

Sl. No.	Import Items	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy and General Notes.

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

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

Case No.	91 / NC/3/MEET/Jan/202425/15
Case Status	Case Rejected
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM REVIW00001056AM25
RA File Number	09AX04000845 AM23
Licence No and Date	0911005139/01/06/2023
Norms Committee Decision:	
The firm vide letter dated 09/11/2-024 has informed that they have surrendered their above license to RA. Therefore, the Committee decided to close the application of the firm.	

Case No.	92 / NC/3/MEET/Jan/202425/15																
Case Status	Case Approved																
Party Name	AMOLI ORGANICS PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025																
HQ File Number	HQRNORM APPLY 00001261AM24																
RA File Number	03AX04000895 AM24																
Licence No and Date	0311024147/02/06/2023																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Clotrimazole USP / BP / EP / IH</td><td rowspan="2">1 kg.</td><td>1</td><td>Ortho Chloro Phenyl Diphenyl Chloromethane</td><td>1.03 kg.</td></tr><tr><td>2</td><td>Imidazole</td><td>0.310 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Clotrimazole USP / BP / EP / IH	1 kg.	1	Ortho Chloro Phenyl Diphenyl Chloromethane	1.03 kg.	2	Imidazole	0.310 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Clotrimazole USP / BP / EP / IH	1 kg.	1	Ortho Chloro Phenyl Diphenyl Chloromethane	1.03 kg.													
		2	Imidazole	0.310 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	93 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001260AM24
RA File Number	03AX04000922 AM24
Licence No and Date	0311024145/02/06/2023
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.
Clotrimazole USP / BP / EP / IH	1 kg.	1	Ortho Chloro Phenyl Diphenyl Chloromethane	1.03 kg.
		2	Imidazole	0.310 kg.

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

Case No.	94 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001257AM24
RA File Number	03AX04000921 AM24
Licence No and Date	0311024140/02/06/2023

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, it was decided to fix ad-hoc norms as under:-

Sl. No	Export Product	Quantity
1	MEDICAL CREAM OINTMENT GEL(Clotrimazole 1 % Cream 1/2 OZ 14 Gm Tube Total Wt: 840Kgs (Net Cont: Clotri 8.62Kgs, Ceto 84Kgs, Octy 113.4Kgs, Cetyl 25.20Kgs, Sorb 16.80Kgs, Poly 12.60Kgs, Benzyl 8.4Kgs))	1 Number
2	MEDICAL CREAM OINTMENT GEL(Clotrimazole 1 % Cream 1 OZ 28 Gm Tube Total Wt: 5320.00Kgs (Net Cont: Clotri 54.56Kgs, Ceto 532Kgs, Octy 718.20Kgs, Cetyl 159.60Kgs, Sorb 106.40Kgs, Poly 79.80Kgs, Benzyl 53.20Kgs))	1 Number
3	MEDICAL CREAM OINTMENT GEL(Clotrimazole 1 % Cream 45 Gm Tube with 1	1 Number

	Applicator Tot Wt: 45Kgs (Net Cont: Clotri 0.46 Kgs, Ceto 4.50 Kgs, Octy 6.08Kgs, Cetyl 1.35Kgs, Sorb 0.90Kgs, Poly 0.68Kgs, Benzyl 0.45Kgs, App 1000 Nos))	
4	MEDICAL CREAM OINTMENT GEL(Clotrimazole 1 % Cream 45 Gm Tube with 7 Applicator Tot Wt: 1530Kgs (Net Cont: Clotri 15.69 Kgs, Ceto 153 Kgs, Octy 206.55 Kgs, Cetyl 45.90 Kgs, Sorb 30.60Kgs, Poly 22.95Kgs, Benzyl 15.30Kgs, App 34000 Nos))	1 Number

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

Note:

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

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

Case No.	95 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	AARTI PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001283AM24
RA File Number	03AX04000485 AM24
Licence No and Date	0311024202/05/06/2023
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.
DI ETHYL SULPHATE	1 kg.	1	ETHANOL	0.746 kg.
		2	SO3	1.29 kg.
		3	SODIUM SULPHATE	0.114 kg.
		4	UREA	0.19 kg.

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

Case No.	96 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
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 cases as per agenda. The representatives of the firm had attended the Personal Hearing through Video Conference. The representative of the firm explained their case and also furnish the information required by TE.

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

Case No.	97 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	INTIGREAT CONSULTING SERVICES LLP

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001324AM24
RA File Number	03AX04000737 AM24
Licence No and Date	0311024265/06/06/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	98 / NC/3/MEET/Jan/202425/15
Case Status	Case Deferred
Party Name	SHILPA PHARMA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001330AM24
RA File Number	07AX04000315 AM24
Licence No and Date	0711007735/06/06/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	99 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001425AM24
RA File Number	03AX04000550 AM24
Licence No and Date	0311024389/09/06/2023
Norms Committee Decision:	
The Committee considered the request of firm in details and also discussed report of factory visit. The committee found that in the above mention case export product is in form of Gel not a cream/Ointments and accordingly decided to fix the ad-hoc norms as under :-	

Sl. No	Export Product	Quantity
(i)	MEDICAL CREAM OINTMENT GEL(Ozonol Ointment 30 Gm Tube (Net Wt: 999.99 Kgs Wax 72 Kgs, Pharmalan 86.90 Kgs, Ichthammol 2.90 Kgs, Orig Oil 4.10 Kgs, Tubes 33333 Nos))	1 Number
(ii)	MEDICAL CREAM OINTMENT GEL(Ozonol Ointment 60 Gm Tube (Net Wt: 2000.04 Kgs Wax 144 Kgs, Pharmalan 173.80 Kgs, Ichthammol 5.80 Kgs, Orig Oil 8.20Kgs, Tubes 33334 Nos))	1 Number

Sl. No.	Import Items	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.
2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy and General Notes.

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

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

Case No.	100 / NC/3/MEET/Jan/202425/15
Case Status	Case Approved
Party Name	UNIMAX LABORATORIES
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202425/ 15 and 28/01/2025
HQ File Number	HQRNORM APPLY 00001505AM24
RA File Number	05AX04000673 AM24
Licence No and Date	0511019298/12/06/2023
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/Mar/202324/25 dated 11/03/2024** against advance authorization **No.0511022259 dated 24/11/2023**, 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.
Azithromycin Tablets 250 mg IP(Each tablet contains : Azithromycin IP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	1	Azithromycin Dihydrate IP	267.27 mg.
Azithromycin Tablets 500 mg IP(Each tablet contains : Azithromycin IP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	2	Azithromycin Dihydrate IP	534.54 mg.
Spiramycin Tablets 1.5 MIU(Each tablet contains Spiramycin EP 1.5 million i.u. Eq. to (379.12 mg / tablet))	1 Number	3	Spiramycin EP	373.02 mg.
Spiramycin Tablets 3.0 MIU(Each tablet contains Spiramycin EP 1.5 million i.u. Eq. to (758.24 mg / tablet))	1 Number	4	Spiramycin EP	Does not match with DML
Azithromycin Tablets 250 mg USP(Each tablet contains : Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	5	Azithromycin Dihydrate USP	267.27 mg.
Azithromycin Tablets 500 mg USP(Each tablet contains : Azithromycin USP (As Dihydrate) Eq. to Anhydrous Azithromycin)	1 Number	6	Azithromycin Dihydrate USP	534.54 mg.

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