



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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(DES - III SECTION)**MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Dec/202425/13**DATED:** 07/01/2025Please 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/Dec/202425/13 dated 07/01/2025 of Norms Committee - III for the year 2024-25 was held on 07/01/2025 under the Chairmanship of 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	UTTAM SARKAR, Assistant Section Officer	DGFT(HQ)
2	Raman Kumar, Deputy DGFT	DGFT(HQ)
3	NAND Lal, Technical Consultant	DPIIT
4	SHAISH KUMAR, Technical Consultant	DGFT
5	DINESHNARAIN MATHUR, Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Dec/202425/13										
Case Status	Case Approved										
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025										
HQ File Number	HQRNORM APPLY 00000293AM25										
RA File Number	NA										
Licence No and Date	NA										
Norms Committee Decision:											
Decision: The Committee considered the request of firm for fixation of ad-hoc norms to enable them to obtain Advance Authorization from concerned RA and it was decided to fix ad-hoc norms as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>62/0- Dihydromyrcenol</td><td>81400 kg.</td><td>1</td><td>Dihydromyrcene</td><td>110000 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	62/0- Dihydromyrcenol	81400 kg.	1	Dihydromyrcene	110000 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
62/0- Dihydromyrcenol	81400 kg.	1	Dihydromyrcene	110000 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	2 / NC/3/MEET/Dec/202425/13				
Case Status	Case Approved				
Party Name	BIOLOGICAL E. LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025				
HQ File Number	HQRNORM APPLY 00007891AM24				
RA File Number	NA				
Licence No and Date	NA				
Norms Committee Decision:					
Decision: The Committee considered the request of firm for fixation of ad-hoc norms to enable them to obtain Advance Authorization from concerned RA and it was decided to fix ad-hoc norms as per details given below or as applied by the firm, whichever is less:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.

TYPHOID CONJUGATE VACCINE MONOVALENT 5 DOSE 2.5ML VIAL WITH VACCINE VIAL MONITOR (VVM)	10,00,000 Vials.	1	YEAST EXTRACT	135.09 kg.
		2	HYPEP	268.75 kg.
		3	ALUMINIUM CHLORIDE HEXA HYDRATE 6	30.33 kg.
		4	CAPTO Q	2 Liters
		5	Phenyl SEPHAROSE HP RESIN	8 Liters
		6	50L ALLEGRO BAG	10 Numbers
		7	HEAT MARKER VACCINE VIAL MONITOR (VVM Labels)	1010,000 Numbers
		8	GLASS VIALS	10,20,000 Numbers
		9	SHIPPING INDICATORS (Q TAGS)	660 Numbers
		10	RUBBER STOPPERS	10,20,000 Numbers
		11	FILTERS & FILTER AIDS	21 Numbers

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

Case No.	3 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	NECTAR LIFE SCIENCES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00001482AM25
RA File Number	222404000083 AM14
Licence No and Date	2210015019/15/07/2014
Norms Committee Decision: The Committee considered the 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: 1. Drug Manufacturing License 2. Annexure to Appendix-4E	

Case No.	4 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00007896AM24
RA File Number	072404000347 AM16
Licence No and Date	0710109255/12/01/2016
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	5 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00000261AM24
RA File Number	039404000617 AM17
Licence No and Date	0310808312/06/10/2016
Norms Committee Decision: Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	6 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025

HQ File Number	HQRNORM REVIW00000263AM24
RA File Number	039404001181 AM17
Licence No and Date	0310812323/03/04/2017
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	7 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00000262AM24
RA File Number	039404000295 AM18
Licence No and Date	0310814908/31/07/2017
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	8 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00000265AM24
RA File Number	039404000822 AM18
Licence No and Date	0310818765/30/01/2018
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	9 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	PALADIN PAINTS & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00001511AM25
RA File Number	039504000456 AM19
Licence No and Date	0310823254/24/08/2018
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PPA-7169 (PHENALKAMINE EPOXY HARDENER) (AMINE FUNCTION COMPOUND)	100 kg.	8	ETHYLENEDIAMINE(EDA)	12.326 kg
		14	PARAFORMALDEHYDE	7.706 kg
		22	BISPHENOL - A	6.219 kg
		28	GY – 250 (unmodified Epoxy Resin)	9.483 kg
PPA-7169 (PHENALKAMINE EPOXY HARDENER) (AMINE FUNCTION COMPOUND)	100 kg.	9	ETHYLENEDIAMINE(EDA)	8.890 kg
		15	PARAFORMALDEHYDE	6.935 kg
		23	BISPHENOL - A	5.96 kg
		29	GY – 250 (unmodified Epoxy Resin)	8.99 kg
PPA-7124 (PHENALKAMIDE EPOXY HARDENER) (AMINE FUNCTION COMPOUND)	100 kg.	1	DIETHYLENE TRRIAMINE (DETA)	25.663kg
		16	PARAFORMALDEHYDE	11.60 kg
		30	GY – 250 (unmodified Epoxy Resin)	10.33 kg
PPA-7558 LITE (PHENALKAMINE EPOXY HARDENER) (AMINE FUNCTION COMPOUND)	100 kg.	2	DIETHYLENE TRRIAMINE (DETA)	8.0 kg
		10	ETHYLENEDIAMINE(EDA)	13.0 kg
		17	PARAFORMALDEHYDE	9.706 kg

		24	BISPHENOL - A	5.98 kg
		31	GY – 250 (unmodified Epoxy Resin)	1.29 kg
PPA-7566 LITE (PHENALKAMINE EPOXY HARDENER) (AMINE FUNCTION COMPOUND)	100 kg.	3	DIETHYLENE TRRIAMINE (DETA)	7.406 kg
		7	META-XYLENEDIAMINE (MXDA)	4.36 kg
		11	ETHYLENEDIAMINE(EDA)	8.872 kg
		18	PARAFORMALDEHYDE	9.367 kg
		25	BISPHENOL - A	4.960 kg
		32	GY – 250 (unmodified Epoxy Resin)	1.61 kg
PPA-7040 LITE (PHENALKAMINE EPOXY HARDENER) (AMINE FUNCTION COMPOUND)	100 kg.	4	DIETHYLENE TRRIAMINE (DETA)	36.487 kg
		19	PARAFORMALDEHYDE	14.98 kg
PPA-7553 (PHENALKAMINE EPOXY HARDENER) (AMINE FUNCTION COMPOUND)	100 kg.	5	DIETHYLENE TRRIAMINE (DETA)	7.203 kg
		12	ETHYLENEDIAMINE(EDA)	15.666 kg
		20	PARAFORMALDEHYDE	14.199 kg
		26	BISPHENOL - A	3.635 kg
		30	GY – 250 (unmodified Epoxy Resin)	3.000 kg
PPA-7062 I (PHENALKAMINE	100 kg.	6	DIETHYLENE TRRIAMINE	6.605 kg

EPOXY HARDENER) (AMINE FUNCTION COMPOUND)		(DETA)	
	13	ETHYLENEDIAMINE(EDA)	5.549 kg
	21	PARAFORMALDEHYDE	9.111 kg
	27	BISPHENOL - A	5.229 kg
	34	GY – 250 (unmodified Epoxy Resin)	4.221 kg

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

Case No.	10 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00002022AM25
RA File Number	052304000507 AM19
Licence No and Date	0510409676/15/02/2019
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant information / documents from the firm.	

Case No.	11 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00007594AM24
RA File Number	039404001019 AM19
Licence No and Date	0310827414/01/03/2019
Norms Committee Decision:	

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

Case No.	12 / NC/3/MEET/Dec/202425/13
Case Status	Case Rejected
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00002204AM23
RA File Number	052304000048 AM20
Licence No and Date	0510410475/03/05/2019

Norms Committee Decision:

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

Case No.	13 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00002357AM25
RA File Number	092404000172 AM20
Licence No and Date	0910067749/03/07/2019

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Jun/202425/5 dated 14/06/2024** against advance authorization **No.0910067749 dated 03/07/2019**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride of Aminoalcohol	1 kg.	1	KRED LYOPHILIZED ENZYME POWDER	0.014 kg.

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

Case No.	14 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00000048AM25
RA File Number	318304000087 AM20
Licence No and Date	3110067548/30/09/2019

Norms Committee Decision:

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. Reason for submitting revised GST certificate for production/consumption data.**
- 2. To give complete calculation with step wise yield of reaction and justification for enhanced quantity of import items which were approved earlier by Norms Committee.**
- 3. Production/consumption data for the last three years duly certificate by Chartered Accountant.**

Case No.	15 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00002927AM25
RA File Number	039404000688 AM20
Licence No and Date	0310833118/02/12/2019

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Dec/202324/17 dated 20/12/2023** against advance authorization **No.0310838377 dated 21/09/2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SODIUM CROMOGLICATE EYE DROPS 13.5 ML	1 Vial	1	SODIUM CROMOGLYCAT	0.2835 gm/13.5 ml pack

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

Case No.	16 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	DIPS BIOSCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00003330AM25
RA File Number	039404000788 AM20
Licence No and Date	0310833754/27/12/2019

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Agrozen forte 23.6gm. Each sachet 23.6 gm contains - (a) Diminazene Diaceturate BP Vet 10.5 gm, (b) Vitamin B12 BP 10.0 mg, (c) Vitamin B6 BP 50.0 mg, (d) Excipients (Phenazone BP) 13.04 gm (30000 Boxes, Box of 10 Sachets = Total 300000 Sachets))	1 Number	1	Vitamin B12 BP	10.1 mg.
		2	Phenazone BP	12.436 gm.
Vetozen plus 23.6gm. Each sachet 23.6 gm contains - (a) Diminazene Diaceturate BP Vet 10.5 gm, (b) Vitamin B12 BP 10.0 mg (c) Excipients (Phenazone BP) 13.09 gm (30000 Boxes, Box of 10 Sachets = Total 300000 Sachets))	1 Number	3	Vitamin B12 BP	10.1 mg.
		4	Phenazone BP	12.436 gm.
Appyvet 23.6gm. Each sachet 23.6 gm contains - (a) Diminazene Diaceturate BP Vet 10.5 gm, (b) Vitamin B12 BP 10.0 mg, (c) Excipients (Phenazone BP) 13.09 gm (30000 Boxes, Box of 10 Sachets = Total 300000 Sachets))	1 Number	5	Vitamin B12 BP	10.1 mg.
		6	Phenazone BP	12.436 gm.

Fomizen Plus. Each Sachet 23.6 gm contains - (a) Diminazene Diaceturate BP Vet 10.5 gm,((b) Vitamin B12 BP 10.0 mg, (c) Vitamin B6 BP 50 mg (d) Excipients (Phenazone BP) 13.04 gm (20000 Boxes, Box of 10 Sachets = Total 200000 Sachets))	1 Number	7	Vitamin B12 BP	10.1 mg.
		8	Phenazone BP	12.436 gm.
Trypano Fort. Each Sachet 23.6 gm Contains - (a) Diminazene Diaceturate BP Vet 10.5 gm,((b) Vitamin B12 BP 10mg, (c) Vitamin B6 BP 50 mg, (d) Excipients (Phenazone BP) 13.04 gm (20000 Boxes, Box of 10 Sachets = Total 200000 Sachets))	1 Number	9	Vitamin B12 BP	10.1 mg.
		10	Phenazone BP	12.436 gm.
Synozen Plus. Each Sachet 23.6 gm Contains - (a) Diminazene Diaceturate BP Vet 10.5 gm,((b) Vitamin B12 BP 10 mg (c) Vitamin B6 BP 50 mg, (d) Excipients (Phenazone BP) 13.04 gm (20000 Boxes, Box of 10 Sachets = Total 200000 Sachets))	1 Number	11	Vitamin B12 BP	10.1 mg.
		12	Phenazone BP	12.436 gm.
Thryptazene Forte. Each Sachet 23.6 gm contains - (a) Diminazene Diaceturale BP Vet 10.5 gm,((b) Vitamin B12 BP 10.0 mg, (c) Vitamin B6 BP 50 mg, (d) Excipients (Phenazone BP) 13.04 gm (23920 Boxes, Box of 10 Sachets = Total 239200 Sachets))	1 Number	13	Vitamin B12 BP	10.1 mg.
		14	Phenazone BP	12.436 gm.

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

Case No.	17 / NC/3/MEET/Dec/202425/13
Case Status	Case Rejected
Party Name	REFLUX PHARMACEUTICALS
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00001943AM25
RA File Number	039504000931 AM20
Licence No and	0310833815/01/01/2020

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

Case No.	18 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	STRIDES ALATHUR PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	018305000750AM20
RA File Number	092404000575 AM20
Licence No and Date	0910068524/28/02/2020

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Dec/202425/12 dated 10/12/2024** against advance authorization **No.0911000444 dated 26/02/2021**, 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.
Memantine Hydrochloride Tablets USP 5Mg - 60s	1 Number	1	Memantine Hydrochloride USP	5.10 mg.
		5	Silicified Microcrystalline Cellulose (Prosolv SMCC 90)	197.00 mg.
		9	Croscarmellose Sodium (Ac Di Sol)	3.00 mg.
		13	Colloidal Silicon dioxide (Aerosil-200)	1.50 mg.
		17	Magnesium Stearate	1.50 mg.

			(Mallinckrodt 2257)	
Memantine Hydrochloride Tablets USP 5Mg - 500s	1 Number	2	Memantine Hydrochloride USP	5.10 mg.
		6	Silicified Microcrystalline Cellulose (Prosolv SMCC 90)	197.00 mg.
		10	Croscarmellose Sodium (Ac Di Sol)	3.00 mg.
		14	Colloidal Silicon dioxide (Aerosil-200)	1.50 mg.
		18	Magnesium Stearate (Mallinckrodt 2257)	1.50 mg.
Memantine Hydrochloride Tablets USP 10Mg - 60s	1 Number	3	Memantine Hydrochloride USP	10.20 mg.
		7	Silicified Microcrystalline Cellulose (Prosolv SMCC 90)	192.00 mg.
		11	Croscarmellose Sodium (Ac Di Sol)	3.00 mg.
		15	Colloidal Silicon dioxide (Aerosil-200)	1.50 mg.
		19	Magnesium Stearate (Mallinckrodt 2257)	1.50 mg.
Memantine Hydrochloride Tablets USP 10Mg - 500s	1 Number	4	Memantine Hydrochloride USP	10.20 mg.

		8	Silicified Microcrystalline Cellulose (Prosolv SMCC 90)	192.00 mg.
		12	Croscarmellose Sodium (Ac Di Sol)	3.00 mg.
		16	Colloidal Silicon dioxide (Aerosil-200)	1.50 mg.
		20	Magnesium Stearate (Mallinckrodt 2257)	1.50 mg.

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

Case No.	19 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	DELTA FINOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00003546AM23
RA File Number	039404000112 AM21
Licence No and Date	0310836419/29/05/2020

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4 Bromobenzaldehyde	1 kg.	1	Liquid Bromine	1.1226 kg.
		2	Hexamine	1.010 kg.
		3	Isopropanol (synonyms Iso Propyl Alcohol)	0.433 kg.

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

Case No.	20 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00000095AM24
RA File Number	522404000013 AM21
Licence No and Date	5210043424/08/06/2020
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant information / documents from the firm:	

Case No.	21 / NC/3/MEET/Dec/202425/13										
Case Status	Case Approved										
Party Name	SYNTHO CHIRALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025										
HQ File Number	HQRNORM REVIW00002342AM25										
RA File Number	092404000185 AM21										
Licence No and Date	0910068991/22/07/2020										
Norms Committee Decision:											
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>(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride</td><td>1 kg.</td><td>1</td><td>CDX-034 LYOPHILIZED ENZYME POWDER</td><td>0.0154 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.0154 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.0154 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	22 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00000254AM24
RA File Number	03AA04011698 AM21
Licence No and Date	0311000235/21/12/2020
Norms Committee Decision: Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	23 / NC/3/MEET/Dec/202425/13
Case Status	Case Rejected
Party Name	REFLUX PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00001944AM25
RA File Number	NA
Licence No and Date	0311001445/03/02/2021
Norms Committee Decision: Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	24 / NC/3/MEET/Dec/202425/13			
Case Status	Case Approved			
Party Name	SYNTHO CHIRALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025			
HQ File Number	HQRNORM REVIW00002353AM25			
RA File Number	09AA04007265 AM22			
Licence No and Date	0911001194/12/07/2021			
Norms Committee Decision: 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.

(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.0154 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	25 / NC/3/MEET/Dec/202425/13
Case Status	Case Rejected
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00193597AM22
RA File Number	03AA04097753 AM22
Licence No and Date	0311007198/25/09/2021
Norms Committee Decision:	
Decision: The firm has informed that they have surrendered their above license to RA. Therefore, the Committee decided to close the application of the firm.	

Case No.	26 / NC/3/MEET/Dec/202425/13
Case Status	Case Rejected
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00008200AM24
RA File Number	05AA040108247 AM22
Licence No and Date	0511006681/07/12/2021
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case.	

Case No.	27 / NC/3/MEET/Dec/202425/13
Case Status	Case Rejected
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00008265AM24
RA File Number	05AX04000189 AM22
Licence No and	0511007079/21/12/2021

Date	
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case.	

Case No.	28 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00299344AM22
RA File Number	07AA04038998 AM22
Licence No and Date	0711002737/28/12/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Calcium Dobesilate Monohydrate BP/ Calcium Dobesilate Monohydrate Eur.Ph / Calcium Dobesilate	1 kg.	1	HYDROQUINONE	0.631 kg.
Etamsylate	1 kg.	2	HYDROQUINONE	0.527 kg.

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

Case No.	29 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	KRUNAL INDUSTRIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00301989AM22
RA File Number	08AX04000162 AM22
Licence No and Date	0811003592/30/12/2021
Norms Committee Decision:	

Decision: The committee considered the request of firm for fixation of ad-hoc norms and it has been observed that the firm has still not furnished the information/documents as sought by Committee earlier in the meeting held on 28.08.2024. Therefore, the Committee has decided to give last chance to the firm to furnish the following information/documents:-

1. **Justification for low yield.**
2. **Production / Consumption data for the year 2021-22 duly certified by the Auditor of the firm.**

Case No.	30 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	PANACEA BIOTEC PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00005946AM24
RA File Number	05AX04000321 AM22
Licence No and Date	0511007823/11/01/2022
Norms Committee Decision:	
Decision: The committee considered the request of firm for fixation of ad-hoc norms and it has been observed that the firm still not furnished the information/documents as sought by Deptt. of Bio-Technology during personal hearing held on 11.11.2024. Therefore, the committee decided to give one more chance to the firm to furnish the reply to Deptt. of Bio-Technnology under intimation to the Committee.	

Case No.	31 / NC/3/MEET/Dec/202425/13
Case Status	Case Rejected
Party Name	GANGWAL HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00356909AM22
RA File Number	03AX04001205 AM22
Licence No and Date	0311011422/16/02/2022
Norms Committee Decision:	
Decision: The firm has informed that they have surrendered their above license to RA. Therefore, the Committee decided to close the application of the firm.	

Case No.	32 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025

HQ File Number	HQRNORM APPLY 00409480AM22
RA File Number	34AX04000458 AM22
Licence No and Date	3411002061/31/03/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Chlorthalidone Tabs USP 25 mg	1 Number	1	Chlorthalidone (Micronized)	25.50 mg.
		2	Microcrystalline Cellulose (Avicel PH 101)	37.45 mg.
		3	Pregelatinized corn starch (Lycatab PGS)	5.00 mg.
		4	Sodium Starch Glycolate (Type A) (EXPLOTAB)	1.50 mg.
		5	Colloidal Silicon Dioxide (Aerosil 200 Pharma)	0.30 mg.
Chlorthalidone Tabs USP 50 mg	1 Number	6	Chlorthalidone (Micronized)	51.00 mg.
		7	Microcrystalline Cellulose (Avicel PH 101)	74.90 mg.
		8	Pregelatinized corn starch (Lycatab PGS)	10.00 mg.
		9	Sodium Starch Glycolate (Type A) (EXPLOTAB)	3.00 mg.
		10	Colloidal Silicon Dioxide	0.60 mg.

			(Aerosil 200 Pharma)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	33 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	ZENFOLD SUSTAINABLE TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001090AM23
RA File Number	09AX04000132 AM23
Licence No and Date	0911003083/31/05/2022
Norms Committee Decision:	
Decision: The committee considered the request of firm for fixation of ad-hoc norms and it has been observed that the firm has not furnished complete reply of DL. Therefore it was decided to call for following information/documents from the firm:- I. Percentage Yield at every stage not given II. Stichometric balance on molar basis not given to justify the quantity of import asked for.	

Case No.	34 / NC/3/MEET/Dec/202425/13										
Case Status	Case Approved										
Party Name	NASENSE LABS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025										
HQ File Number	HQRNORM APPLY 00001297AM23										
RA File Number	09AX04000213 AM23										
Licence No and Date	0911003160/09/06/2022										
Norms Committee Decision:											
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>4 Dimethyl Aminopyridine</td><td>1 kg.</td><td>1</td><td>4-Cyanopyridine</td><td>1.0 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	4 Dimethyl Aminopyridine	1 kg.	1	4-Cyanopyridine	1.0 kg.
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)	1.07 kg,
		3	Acrylic Acid	0.694 kg.
		4	Dimethylamine 40 percent Solution	0.08
		5	Caustic Soda Flakes	Not allowed as fully recovered
		6	Toluene	1.15 kg.

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

Case No.	35 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001347AM23
RA File Number	05AX04000669 AM23
Licence No and Date	0511013173/13/06/2022
Norms Committee Decision:	
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:- To give a balanced chemical reaction indicating molecular weight of all the reactants and product with stage wise yield of the reaction. To indicate where AluminoSilicate catalyst, Denatured Ethyl alcohol and methanol are used in the chemical reaction giving their application/use. Calculation of the requirement of all the chemicals with justification of low yield.	

Case No.	36 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001993AM23

RA File Number	34AX04000353 AM23
Licence No and Date	3411002522/12/07/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	37 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002011AM23
RA File Number	52AX04001578 AM23
Licence No and Date	5211002817/13/07/2022
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant information / documents from the firm:	

Case No.	38 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002019AM23
RA File Number	09AX04000338 AM23
Licence No and Date	0911003340/13/07/2022
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

		4	Acetone	0.69 kg.
		5	Aqueous Dimethyl Amine	1.64 kg.
		6	Acetic Acid	0.47 kg.
		7	CBZ - L - Valine	1.112 kg.
		8	Dimethyl carbonyl chloride	0.98 kg.
		9	Dimethylaminopyridine	0.028 kg.
		10	Dimethyl formamide	1.92 kg.
		11	methanol	4.82 kg.
		12	Isopropanol	2.55 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	39 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002358AM23
RA File Number	34AX04000398 AM23
Licence No and Date	3411002586/29/07/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	40 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002124AM25

RA File Number	NA													
Licence No and Date	0511014073/02/08/2022													
Norms Committee Decision:														
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<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>Desmopressin Acetate Nasal Solution 0.01% (Nasal Spray) 5ml/Vial, Each ml contains 0.1mg (Equivalent to qty Desmopressin Acetate 500.000 Gm)</td> <td>1 Number</td> <td>1</td> <td>Desmopressin Acetate</td> <td>510 gm.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Desmopressin Acetate Nasal Solution 0.01% (Nasal Spray) 5ml/Vial, Each ml contains 0.1mg (Equivalent to qty Desmopressin Acetate 500.000 Gm)	1 Number	1	Desmopressin Acetate	510 gm.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Desmopressin Acetate Nasal Solution 0.01% (Nasal Spray) 5ml/Vial, Each ml contains 0.1mg (Equivalent to qty Desmopressin Acetate 500.000 Gm)	1 Number	1	Desmopressin Acetate	510 gm.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	41 / NC/3/MEET/Dec/202425/13													
Case Status	Case Approved													
Party Name	ALEMBIC PHARMACEUTICALS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025													
HQ File Number	HQRNORM APPLY 00002474AM23													
RA File Number	34AX04000434 AM23													
Licence No and Date	3411002610/04/08/2022													
Norms Committee Decision:														
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<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>Midodrine HCL Tabs USP 2.5 mg</td> <td>1 Number</td> <td>1</td> <td>Midodrine Hydrochloride USP (Micronized)</td> <td>2.55 mg.</td> </tr> </tbody> </table>					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.
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.	42 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002477AM23
RA File Number	09AX04000348 AM23
Licence No and Date	0911003442/04/08/2022

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Jan/202021/4 dated 12/02/2021** against advance authorization **No.0910068698 dated 29/04/2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BOLT ENERGY EFFERVESCENT TABLETS ((Each Tablet Contains - Glucuronolactone 50 mg, Ascorbic Acid 300 mg,Caffeine 50mg))	1 Number Tablet	1	Glucuronolactone	51.00 mg
		2	Ascorbic Acid (Crystalline)	306.0 mg.
		3	Caffeine Anhydrous	51.00 mg.
		4	Sodium Polyphosphate	50.00 mg.
		5	Sodium Hydrogen Carbonate	950.00 mg.

		6	Gin Fizz Micron Flavour	30.00 mg.
		7	Macrogol 6000	135.00 mg.
		8	Monosodium Fumarate	2000.00 mg.

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

Case No.	43 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002548AM23
RA File Number	03AX04002511 AM23
Licence No and Date	0311017048/10/08/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SECNIDAZOLE PELLETS (Secnidazole taste masked pellets) (each gm contains 473.5 mg a.i.)	1 kg.	1	SECNIDAZOLE IH	0.478 kg.

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

Case No.	44 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	GUJARAT FLUOROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002598AM23
RA File Number	34AX04000342 AM23

Licence No and Date	3411002640/11/08/2022			
Norms Committee Decision:				
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
R142B (1-Chloro 1,1-Difluoroethane)	1 kg.	1	1-1-Dichloroethene (Vinylidene Chloride)	1.00 kg.
		2	Fluorspar	Deleted
		3	Tintetrachloride	Deleted
Note: The above ad-norms were fixed only for this license.				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	45 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002645AM23
RA File Number	03AX04002727 AM23
Licence No and Date	0311017254/16/08/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	46 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002801AM23

RA File Number	09AX04000470 AM23
Licence No and Date	0911003541/26/08/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2butyl16dihydro- NN,4trimethyl6oxo- 1[[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	N-(Triphenylmethyl)-5-(4-Bromomethylbiphenyl-2-yl-) Tetrazole	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.	47 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002813AM23
RA File Number	07AX04000768 AM23
Licence No and Date	0711005110/26/08/2022

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jun/202324/6 dated 14/06/2024** against advance authorization No. **0711006656 dated 07/03/2023**, it was decided to fix adhoc 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.
MAGNESIUM CITRATE (USP/ NONAHYDRATE Eur.Ph/ ANHYDROUS Eur.Ph/ DODECAHYDRATE Eur.Ph)	1 kg.	1	CITRIC ACID	1.001 kg.
		2	MAGNESIUM CARBONATE	0.730 kg.
CALCIUM CITRATE(USP)	1 kg.	3	CITRIC ACID	0.816 kg.
		4	CALCIUM CARBONATE	0.660 kg.
ZINC CITRATE(USP)	1 kg.	5	CITRIC ACID	0.880 kg.
POTASSIUM CITRATE (BP/Eur.Ph/ USP)	1 kg.	6	CITRIC ACID	0.859 kg.
		7	POTASSIUM CARBONATE GRANULAR	Deleted

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

Case No.	48 / NC/3/MEET/Dec/202425/13			
Case Status	Case Approved			
Party Name	GODAVARI BIOREFINERIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025			
HQ File Number	HQRNORM APPLY 00002842AM23			
RA File Number	03AX04002739 AM23			
Licence No and Date	0311017558/29/08/2022			
Norms Committee Decision:				
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

		No.		
3-METHYL-3-PENTEN-2-ONE	1 kg.	1	Methyl Ethyl Ketone	0.864 kg.
		2	DENATURE ETHYL ALCOHOL	0.626 kg.

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

Case No.	49 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002919AM23
RA File Number	34AX04000543 AM23
Licence No and Date	3411002729/02/09/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	50 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	INTIGREAT CONSULTING SERVICES LLP
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00003056AM23
RA File Number	03AX04002543 AM23
Licence No and Date	0311017790/12/09/2022
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	51 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00003118AM23

RA File Number	09AX04000498 AM23
Licence No and Date	0911003623/14/09/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	52 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00003251AM23
RA File Number	34AX04000590 AM23
Licence No and Date	3411002800/21/09/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	53 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00006256AM24
RA File Number	08AX04000971 AM23
Licence No and Date	0811006083/22/09/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	54 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	KAVALIFE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00003326AM23
RA File Number	07AX04000884 AM23
Licence No and Date	0711005312/23/09/2022
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending	

Personal Hearing before Norms Committee to explain its case along with relevant information / documents from the firm:

Case No.	55 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	ALIVUS LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00003339AM23
RA File Number	03AX04003267 AM23
Licence No and Date	0311018114/24/09/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	56 / NC/3/MEET/Dec/202425/13			
Case Status	Case Approved			
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025			
HQ File Number	HQRNORM APPLY 00003366AM23			
RA File Number	03AX04003250 AM23			
Licence No and Date	0311018155/25/09/2022			
Norms Committee Decision:				
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Case No.	57 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00006048AM23
RA File Number	07AX04001667 AM23
Licence No and Date	0711006347/02/02/2023

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Nov/202425/10 dated 22/11/2024** against advance authorization **No.0711011361 dated 24/05/2024** , 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.
RAMELTEON 8 MG TABLETS	1 Number Tablet	1	RAMELTEON	8.16 mg/Tablet

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

Case No.	58 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	SYNERGIA SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00006312AM23
RA File Number	03AX04005369 AM23
Licence No and Date	0311021429/14/02/2023

Norms Committee Decision:

After going through the application filed at the time of issuance of authorisation, the committee observed that the firm wants to import two alternate inputs in the same quantity for the same export product. As per the FTP/HBP provisions, the Advance authorisation scheme doesn't provide for two substitute/alternate inputs. Therefore, the Committee decided to call for the following information/documents from the firm:-

I. Clarification regarding the unusable quantity of Alpha picoline and why it cannot be used and

also the yield of 50.4% in first stage.

II. GST certified data for production/consumption quantity of export made from raw material 2-Ethanol Pyridine and Secondary Butyl Chloroformate.

Case No.	59 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	AZAKEM LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00000910AM24
RA File Number	09AX04000127 AM24
Licence No and Date	0911005042/17/05/2023
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	60 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	VASISTA PHARMA CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001152AM24
RA File Number	26AX04000028 AM24
Licence No and Date	2611000961/26/05/2023
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	61 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002558AM24
RA File Number	07AX04000359 AM24
Licence No and Date	0711008395/26/06/2023
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MAGNOLIAL (2,4-dimethyl-4,4a,5,9b-tetrahydroindeno[1,2-d][1,3]dioxine CAS NO.27606-09-3)	1 kg.	1	INDENE (92-94% purity)	1.12 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	62 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00004244AM24
RA File Number	09AX04000203 AM24
Licence No and Date	0911005339/06/07/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
N Butyl Lithium 15% /23% /30% w/w in Hexane (100% Active basis)	1 kg.	1	N-Butyl Chloride	0.6 kg.
		2	Lithium Metal	0.09 kg.
		3	n-Hexane	0.84 kg.

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

Case No.	63 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	GITANJALI CHEMICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025			
HQ File Number	HQRNORM APPLY 00004784AM24			
RA File Number	03AX04001927 AM24			
Licence No and Date	0311025944/02/08/2023			
Norms Committee Decision:				
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Case No.	64 / NC/3/MEET/Dec/202425/13
Case Status	Case Rejected
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM REVIW00003678AM25
RA File Number	09AX04000551 AM24
Licence No and Date	0911005810/20/09/2023
Norms Committee Decision:	
Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	65 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	PRASOL CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00008287AM24
RA File Number	03AX04004987 AM24
Licence No and Date	0311030614/01/02/2024
Norms Committee Decision:	

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. **Manufacturing process starting from Acetone.**
2. **Molecular weight and percentage of yield at every stage of reaction.**
3. **Stichiometric balance for chemical reaction.**

Case No.	66 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	YELLOWSTONE FINE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00008613AM24
RA File Number	03AX04005249 AM24
Licence No and Date	0311031269/16/02/2024

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. **Molecular weigh of export product.**
2. **Yield at every stage of reaction.**
3. **Stichiometric balance with percentage of yield on molar basis to arrive at the quantity of raw material asked.**

Case No.	67 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00008718AM24
RA File Number	03AX04005330 AM24
Licence No and Date	0311031439/23/02/2024

Norms Committee Decision:

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

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

YODANOL (a,y-dimethyl-benzenepentanol)	1 kg.	1	Benzaldehyde	0.790 kg.
		2	N-HEPTANE	0.029 kg.
		3	Camphor sulfonic acid	0.005 kg.
		4	SYNPERONIC T/1301-LQ-(CQ)	0.08 kg.
		5	Primol 352	0.09 kg.

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

Case No.	68 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	SYNERGIA SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00000333AM25
RA File Number	03AX04000023 AM25
Licence No and Date	0311033222/19/04/2024
Norms Committee Decision: After going through the application filed at the time of issuance of authorisation, the committee observed that the firm wants to import two alternate inputs in the same quantity for the same export product. As per the FTP/HBP provisions, the Advance authorisation scheme doesn't provide for two substitute/alternate inputs. Therefore, the Committee decided to call for the following information/documents from the firm:- I. Clarification regarding the unusable quantity of Alpha picoline and why it cannot be used and also the yield of 50.4% in first stage. II. GST certified data for production/consumption quantity of export made from raw material 2-Ethanol Pyridine and Secondary Butyl Chloroformate.	

Case No.	69 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001762AM25
RA File Number	03AX04001633 AM25
Licence No and	0311035236/05/07/2024

Date	
Norms Committee Decision: 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.	

Case No.	70 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001763AM25
RA File Number	31AX04000098 AM25
Licence No and Date	3111003647/05/07/2024
Norms Committee Decision: 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. Justification for low yield of reaction for the items acetone, Ammonia and hydrogen peroxide. 2. The function of Methylene Dichloride in the reaction and its recovery details in the process. 3. Stoichiometric material balance on molar basis. 4. The commercial value of by-product Caustic soda lye.	

Case No.	71 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001769AM25
RA File Number	07AX04000561 AM25
Licence No and Date	0711011739/05/07/2024
Norms Committee Decision: 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. Whether the item of export will be covered under Vitamin category?	

2. Whether the import item 'Orotic Acid' is a vitamin?

Case No.	72 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	COHANCE LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001770AM25
RA File Number	09AX04000214 AM25
Licence No and Date	0911007551/05/07/2024

Norms Committee Decision:

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. Composition of import item**
- 2. Certificate of Analysis (CoA) from Foreign Supplier.**
- 3. Copy of Drug Manufacturing License (DML).**
- 4. Wastage applied.**

Case No.	73 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001796AM25
RA File Number	03AX04001674 AM25
Licence No and Date	0311035257/07/07/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Sep/202324/13 dated 14/09/2023** against advance authorization **No.0311025115 dated 04/07/2023**, 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.
Colesevelam Hydrochloride for oral suspension 3.75GM	41000 Packs	1	Colesevelam Hydrochloride	4843.12 kg.

(Per Pack 30 Pouches)				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	74 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001797AM25
RA File Number	03AX04001664 AM25
Licence No and Date	0311035262/08/07/2024

Norms Committee Decision:

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 Ointment cream lotion(Lidocaine and Prilocaine Cream USP, 2.5% , 2.5%,30g Tot Wt. 19500 Kgs (Net Cont. Lidocaine 487.50 Kgs, Prilocaine 487.50 Kgs, Carbopol 195 Kgs, PEG-60 370.50 Kgs tubes 65000 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.	75 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	ABRYL LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001806AM25
RA File Number	30AX04000117 AM25
Licence No and Date	3011005434/08/07/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dexketoprofen 50mg/2ml solution for Injection (Ampoules) (Dexketoprofen 50mg/2ml equivalent to 73.80 mg of Dexketoprofen trometamol)	1 Number	1	Dexketoprofen Trometamol	55.00 mg.

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

Case No.	76 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	DR.ACHARYA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001817AM25
RA File Number	03AX04001681 AM25
Licence No and Date	0311035296/08/07/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Dec/202425/12 dated 10/12/2024** against advance authorization **No.0311034156 dated 05/06/2024**, 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.
3-Methoxy-2-methylbenzoyl chloride (MMBC)(CAS NO.24487-91-0)	1 kg.	1	3-Methoxy-o-toluic Acid (MOTA)	0.95 kg.

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

Case No.	77 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001818AM25
RA File Number	52AX04000090 AM25
Licence No and Date	5211008811/08/07/2024

Norms Committee Decision:

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

Case No.	78 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001820AM25
RA File Number	52AX04000089 AM25
Licence No and Date	5211008812/08/07/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending

Personal Hearing before Norms Committee to explain its case along with relevant information / documents from the firm.

Case No.	79 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001846AM25
RA File Number	34AX04000273 AM25
Licence No and Date	3411005128/09/07/2024

Norms Committee Decision:

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

- I. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.
- II. Stoichiometric balance between import and export on molar basis.

Case No.	80 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001858AM25
RA File Number	03AX04001750 AM25
Licence No and Date	0311035328/10/07/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.5/82-ALC4/2020 dated 09/10/2020** against advance authorization **No.0310835571 dated 20/03/2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Felodipine ER Tablets 2.5 mg 100's((6,000 Bottles X 100	1 Number	1	Felodipine	2.55 mg/2.5 mg Tablet

Tablets Per Bottles = 6,00,000 Tablets) (Total Weight of Export Product = 1.500 Kgs)	Tablet			
Felodipine ER Tablets 5.0 mg 100's((15,000 Bottles X 100 Tablets Per Bottles = 15,00,000 Tablets) (Total Weight of Export Product = 7.500 Kgs)	1 Number Tablet	2	Felodipine	5.10 mg/5 mg Tablet
Felodipine ER Tablets 10 mg 100's((37,500 Bottles X 100 Tablets Per Bottles = 37,50,000 Tablets) (Total Weight of Export Product = 37.500 Kgs)	1 Number Tablet	3	Felodipine	10.20 mg/10 mg Tablet

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

Case No.	81 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001869AM25
RA File Number	03AX04001782 AM25
Licence No and Date	0311035355/10/07/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRIMETHYLOLPROPANE TRIMETHACRYLATE (TMPTMA 70)	30000 kg.	1	TRIMETHYLOLPROPANE TRIMETHACRYLATE (TMPTMA)	21030 kg.

(Minimum 70% active content)				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	82 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001870AM25
RA File Number	09AX04000225 AM25
Licence No and Date	0911007569/10/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	83 / NC/3/MEET/Dec/202425/13													
Case Status	Case Approved													
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025													
HQ File Number	HQRNORM APPLY 00001871AM25													
RA File Number	03AX04001699 AM25													
Licence No and Date	0311035363/10/07/2024													
Norms Committee Decision:														
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<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.	84 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001896AM25
RA File Number	05AX04000950 AM25
Licence No and Date	0511026636/12/07/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
3-PYRIDINECARBOXYLIC ACID, 2-[(2METHOXYETHOXY) METHYL]-6-(TRIFLUOROMETHYL)-ETHYL ESTER	1 kg.	1	METHOXY-AA TECH. 12 [GB]	0.790 kg.
		2	TOLUENE	0.239 kg.
		3	TRI ETHYL AMINE (TEA)	0.140 kg.
		4	TRICHLOROACETYL CHLORIDE [TCAC]	0.945 kg.
		5	ETHYL VINYL ETHER	0.314 kg.
		6	ACETIC ACID	0.030 kg.
		7	ORTHOXYLENE	0.140 kg.

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

Case No.	85 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025																
HQ File Number	HQRNORM APPLY 00001907AM25																
RA File Number	03AX04001823 AM25																
Licence No and Date	0311035444/12/07/2024																
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <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">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> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					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.													

Case No.	86 / NC/3/MEET/Dec/202425/13													
Case Status	Case Approved													
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025													
HQ File Number	HQRNORM APPLY 00001913AM25													
RA File Number	03AX04001799 AM25													
Licence No and Date	0311035447/12/07/2024													
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <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>Fenofibrate 145mg tablets</td> <td>1 Number</td> <td>1</td> <td>Fenofibrate Micronized IH/Ph Eur</td> <td>147.90 mg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Fenofibrate 145mg tablets	1 Number	1	Fenofibrate Micronized IH/Ph Eur	147.90 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Fenofibrate 145mg tablets	1 Number	1	Fenofibrate Micronized IH/Ph Eur	147.90 mg.										

		2	Sucrose PH.Eur (exepient)	146.45 mg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	87 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001929AM25
RA File Number	08AX04000588 AM25
Licence No and Date	0811012112/15/07/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Dec/202425/12 dated 10/12/2024** against advance authorization **No.0811011790 dated 12/06/2024**, 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.
Calcium Gluconate Injection, USP 1,000 mg per 10 mL (100 mg per mL)	1 Number	1	CALCIUM GLUCONATE MONOHYDRATE USP	1081.0 mg.
Calcium Gluconate Injection, USP 5,000 mg per 50 mL (100 mg per mL)	1 Number	2	CALCIUM GLUCONATE MONOHYDRATE USP	5145.0 mg.
Calcium Gluconate Injection, USP 10,000 mg per 100 mL (100 mg per mL)	1 Number	3	CALCIUM GLUCONATE MONOHYDRATE USP	10290.0 mg.

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

Case No.	88 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001932AM25
RA File Number	09AX04000247 AM25
Licence No and Date	0911007585/15/07/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
N Butyl Lithium 30% w/w in Hexane Solution	1 kg.	1	N-Butyl Chloride	0.6 kg.
		2	Lithium Metal	0.09 kg.
		3	n-Hexane	0.84 kg.

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

Case No.	89 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001938AM25
RA File Number	05AX04001174 AM25
Licence No and Date	0511026672/15/07/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Jun/202324/6 dated 14/06/2024** against advance authorization **No.0511017659 dated 07/03/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TOBRIS (TOBRAMYCIN 0.3 PERCENT) EYE DROPS 5 ML VIAL	1 Number Vial	1	Tobramycin Sulphate	19.057 mg.

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

Case No.	90 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001939AM25
RA File Number	05AX04001182 AM25
Licence No and Date	0511026673/15/07/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.6/82-ALC4/2019 dated 16/08/2019** against advance authorization **No.0510411169 dated 05/07/2019**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DANCIL EYE & EAR DROPS .3% 5 ML VIAL (Each ml of Dancil contains 3mg of Ofloxacin)	1 pack	1	Ofloxacin	0.0153 gm/5 ml. pack

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

Case No.	91 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001940AM25
RA File Number	05AX04001170 AM25

Licence No and Date	0511026674/15/07/2024													
Norms Committee Decision:														
Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aug/202425/8 dated 28/08/2024 against advance authorization No.0511024955 dated 18/04/2024, 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:-														
<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>Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml (Each ml contains 10 mg of Brinzolamide)</td> <td>1 Vial</td> <td>1</td> <td>Brinzolamide Micronized Sterile</td> <td>51.00 mg/Vial</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml (Each ml contains 10 mg of Brinzolamide)	1 Vial	1	Brinzolamide Micronized Sterile	51.00 mg/Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml (Each ml contains 10 mg of Brinzolamide)	1 Vial	1	Brinzolamide Micronized Sterile	51.00 mg/Vial										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	92 / NC/3/MEET/Dec/202425/13													
Case Status	Case Approved													
Party Name	SENTISS PHARMA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025													
HQ File Number	HQRNORM APPLY 00001941AM25													
RA File Number	05AX04001181 AM25													
Licence No and Date	0511026676/15/07/2024													
Norms Committee Decision:														
Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No.0511023042 dated 03/01/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Cyclomed Eye Drops 1% 5ml (Each ml contains 10 mg of Cyclopentolate Hydrochloride)</td> <td>1 Pack</td> <td>1</td> <td>Cyclopentolate HCL USP</td> <td>51.00 mg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Cyclomed Eye Drops 1% 5ml (Each ml contains 10 mg of Cyclopentolate Hydrochloride)	1 Pack	1	Cyclopentolate HCL USP	51.00 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Cyclomed Eye Drops 1% 5ml (Each ml contains 10 mg of Cyclopentolate Hydrochloride)	1 Pack	1	Cyclopentolate HCL USP	51.00 mg.										

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

Case No.	93 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001942AM25
RA File Number	03AX04001857 AM25
Licence No and Date	0311035506/15/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	94 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001953AM25
RA File Number	03AX04001667 AM25
Licence No and Date	0311035539/16/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	95 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001959AM25
RA File Number	03AX04001864 AM25
Licence No and Date	0311035562/16/07/2024
Norms Committee Decision:	
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 Creams & Ointments(Mycospor 1% Cream 10 Gm (Tot Wt: 6000Kgs. Net Cont:Bifonazole JP 60 Kgs,Octyldodecanol JP 810 Kgs, Sorbitan Monostearate JP 120 Kgs, Aluminium Tubes 600,000 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.	96 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001961AM25
RA File Number	03AX04001867 AM25
Licence No and Date	0311035566/16/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	97 / NC/3/MEET/Dec/202425/13
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Case Status	Case Deferred
Party Name	DINAKARA LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001982AM25
RA File Number	09AX04000270 AM25
Licence No and Date	0911007602/18/07/2024
Norms Committee Decision: 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. To give complete chemical reaction (without using abbreviation) indicating molecular weight of reactant and products and calculation of requirement of chemicals. 2. To give stage wise yield of the reaction with justification and Stoichiometric material balance on molar basis. 3. Function of mineral oil in the process and current production/consumption data.	

Case No.	98 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00001994AM25
RA File Number	03AX04001885 AM25
Licence No and Date	0311035597/18/07/2024
Norms Committee Decision: Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	99 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002019AM25
RA File Number	05AX04001273 AM25
Licence No and Date	0511026754/19/07/2024
Norms Committee Decision: Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Dec/202425/12 dated 10/12/2024 against	

advance authorization **No.0511025839 dated 03/06/2024**, 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.
Nitroglycerin Sublingual Tablets USP, 0.3mg	1 Number	1	DILUTED NITROGLYCERIN USP (2% W/W)	15.30 mg.
Nitroglycerin Sublingual Tablets USP, 0.4mg	1 Number	2	DILUTED NITROGLYCERIN USP (2% W/W)	20.40 mg.
Nitroglycerin Sublingual Tablets USP, 0.6mg	1 Number	3	DILUTED NITROGLYCERIN USP (2% W/W)	30.60 mg.

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

Case No.	100 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002025AM25
RA File Number	09AX04000240 AM25
Licence No and Date	0911007615/19/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	101 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002026AM25
RA File Number	09AX04000239 AM25
Licence No and Date	0911007616/19/07/2024
Norms Committee Decision:	

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

Case No.	102 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002039AM25
RA File Number	03AX04001938 AM25
Licence No and Date	0311035673/22/07/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product **No.NC/3/MEET/Aug/202425/8 dated 28/08/2024** against advance authorization **No. 0311032713 dated 01/04/2024** , it was decided 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.
Brimonidine Tartrate /Timolol ophthalmic solution 0.2%/0.5% (5 ml Bottle) ((Each ml Contains : Brimonidine Tartrate 2mgand Timolol Maleate 6.8 mg equivalent to Timolol 5mg) (Each 5 ml Bottle Contains :Brimonidine Tartrate 10mg and Timolol Maleate 34 mg)	1 Number

Brimonidine Tartrate/Timololophthalmic solution 0.2%/0.5% (10ml Bottle) ((Each ml Contains: Brimonidine Tartrate 2mg and Timolol Maleate 6.8mg equivalent to Timolol 5mg) (Each 10 ml Bottle Contains :Brimonidine Tartrate 20mg and Timolol Maleate 68 mg)	1 Number
Brimonidine Tartrate /Timolol ophthalmic solution 0.2%/0.5% (15 ml Bottle)((Each ml Contains : Brimonidine Tartrate 2mg and Timolol Maleate 6.8mg equivalent to Timolol 5mg) (Each 15 ml Contains :Brimonidine Tartrate 30mg and Timolol Maleate 102 mg)	1 Number

DorzolamideHydrochloride- TimololMaleateOphthalmicSolutionUSP(5mlBottle)((EachmlContains:DorzolamideHydrochloride 22.3mg equivalent to Dorzolamide 20mg and Timolol Maleate 6.8mg equivalent to Timolol 5mg) (Each 5ml Contains: Dorzolamide Hydrochloride 111.50mg & Timolol Maleate 34 mg)	1 Number
DorzolamideHydrochloride- TimololMaleateOphthalmicSolutionUSP(10mlBottle)((EachmlContain:DorzolamideHydrochloride 22.3mg equivalent to Dorzolamide 20mg and Timolol Maleate 6.8mg equivalent to Timolol 5mg) (Each 10ml Contains: Dorzolamide Hydrochloride 223 mg & Timolol Maleate 68 mg)	1 Number

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

Case No.	103 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002040AM25
RA File Number	03AX04001939 AM25
Licence No and Date	0311035674/22/07/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Jan/202324/20 dated 18/01/2024** against advance authorization **No. 0311023932 dated 25/05/2023** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ketotifen Fumarate ophthalmic solution 0.035% (5ml Bottle) (Each ml. Contains: Ketotifen (0.025%) Antihistamine (Equivalent to Ketotifen Fumarate 0.035%) = 1.750mg per bottle of 5ml.) (i.e. 1.75mg./5ml) Net Weight in Export Products is: 1001.000 GRAMS)	1 Number	1	Ketotifen Fumarate	1.785 mg.
		2	Bottle	Relevant, as per Packing Policy & General Notes.
		3	Cap	Relevant, as per Packing Policy & General Notes.
		4	Dropper	Relevant, as per Packing Policy & General Notes.

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

Case No.	104 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002042AM25
RA File Number	08AX04000418 AM25
Licence No and Date	0811012178/22/07/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Jun/202324/6 dated 01/07/2024** against advance authorization **No. 3411003955 dated 27/07/2023** , 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.
Metronidazole Gel Usp 1% 55 gm pump	40,000 Numbers	1	Metronidazole (Micronized) USP	22.44 kg.
Metronidazole Gel USP 1% 60 gm tube	70,000 Numbers	2	Metronidazole (Micronized) USP	42.84 kg.

Note: NC also decided to make Standard Input Output Norms (SION) for the above export products based on ad-hoc norms.

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

Case No.	105 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002046AM25

RA File Number	03AX04001493 AM25																
Licence No and Date	0311035695/22/07/2024																
Norms Committee Decision:																	
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<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">Ciprofloxacin Hydrochloride BP/EP/USP</td><td rowspan="2">1 kg.</td><td>1</td><td>Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate</td><td>1.240 kg.</td></tr><tr><td>2</td><td>Piperazine (68%)</td><td>0.574 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ciprofloxacin Hydrochloride BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg.	2	Piperazine (68%)	0.574 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Ciprofloxacin Hydrochloride BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg.													
		2	Piperazine (68%)	0.574 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	106 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002051AM25
RA File Number	34AX04000849 AM24
Licence No and Date	3411005190/22/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	107 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002052AM25
RA File Number	34AX04000306 AM25
Licence No and Date	3411005187/22/07/2024
Norms Committee Decision:	

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Aug/202425/8 dated 28/08/2024** against advance authorization **No. 0811011334 dated 23/04/2024**, 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.
Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% - 15 gm Tube (net content of active ingredients 23.86 kgs.)	1 Number	1	Nystatin USP	238.65 mg.
Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% - 30 gm tube (net content of active ingredients 34.09 kgs.)	1 Number	2	Nystatin USP	477.30 mg.
Nystatin and Triamcinolone Acetonide Ointment USP, 1,00,000 UNITS / GM; 0.1% - 60 gm (net content of active ingredients 40.90 kgs.)	1 Number	3	Nystatin USP	954.61 mg.
Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% - 15 gm tube (net content of active ingredients 23.86 kgs.)	1 Number	4	Nystatin USP	238.65 mg.
Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000 UNITS / GM; 0.1% - 30 gm tube (net content of active ingredients 34.09 kgs.)	1 Number	5	Nystatin USP	477.30 mg.
Nystatin and Triamcinolone Acetonide Cream USP, 1,00,000	1 Number	6	Nystatin USP	954.61 mg.

UNITS / GM; 0.1% - 60 gm tube (net content of active ingredients 40.90 kgs.)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	108 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002058AM25
RA File Number	08AX04000652 AM25
Licence No and Date	0811012185/22/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	109 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002060AM25
RA File Number	05AX04001134 AM25
Licence No and Date	0511026794/22/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	110 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002066AM25
RA File Number	03AX04001974 AM25
Licence No and Date	0311035722/23/07/2024
Norms Committee Decision:	

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

Case No.	111 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002069AM25
RA File Number	03AX04001934 AM25
Licence No and Date	0311035731/23/07/2024

Norms Committee Decision:

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. Full chemical name with details of the export item.
2. Chemical reaction of the reactant and products indicating molecular weight and yield of the reaction with justification.
3. Stoichiometric material balance on molar basis indicating endues of export item

Case No.	112 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002077AM25
RA File Number	08AX04000609 AM25
Licence No and Date	0811012189/23/07/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
APROTININ INJECTION	1 Number Vial	1	APROTININ	15.4 mg.

(100000 KIU, 10ML AMP)				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	113 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	WEST BENGAL CHEMICAL INDUSTRIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002099AM25
RA File Number	02AX04000242 AM25
Licence No and Date	0211006960/23/07/2024
Norms Committee Decision: 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 chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.	

Case No.	114 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	MEONE HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002100AM25
RA File Number	04AX04000340 AM25
Licence No and Date	0411007845/23/07/2024
Norms Committee Decision: Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	115 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002111AM25
RA File Number	07AX04000649 AM25

Licence No and Date	0711011876/24/07/2024			
Norms Committee Decision:				
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Calcium Dobesilate Monohydrate BP/ Calcium Dobesilate Monohydrate Eur.Ph / Calcium Dobesilate	1 kg.	1	HYDROQUINONE	0.631 kg.
Etamsylate	1 kg.	2	HYDROQUINONE	0.527 kg.

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

Case No.	116 / NC/3/MEET/Dec/202425/13										
Case Status	Case Approved										
Party Name	TORRENT PHARMACEUTICALS LTD										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025										
HQ File Number	HQRNORM APPLY 00002123AM25										
RA File Number	08AX04000639 AM25										
Licence No and Date	0811012198/24/07/2024										
Norms Committee Decision:											
Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aug/202425/8 dated 28/08/2024 against advance authorization No. 0811011227 dated 04/04/2024, 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:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>CANDESARTAN CILEXETIL 2 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 2 MG NET CONTENT OF</td><td>1 Number</td><td>1</td><td>CANDESARTAN CILEXETIL PH.EUR</td><td>2.04 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CANDESARTAN CILEXETIL 2 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 2 MG NET CONTENT OF	1 Number	1	CANDESARTAN CILEXETIL PH.EUR	2.04 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
CANDESARTAN CILEXETIL 2 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 2 MG NET CONTENT OF	1 Number	1	CANDESARTAN CILEXETIL PH.EUR	2.04 mg.							

CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 0.180 KG IN EXPORT ITEM)				
CANDESARTAN CILEXETIL 4 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 4 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 1.440 KG IN EXPORT ITEM)	1 Number	2	CANDESARTAN CILEXETIL PH.EUR	4.08 mg.
CANDESARTAN CILEXETIL 8 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 8 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 5.760 KG IN EXPORT ITEM)	1 Number	3	CANDESARTAN CILEXETIL PH.EUR	8.16 mg.
CANDESARTAN CILEXETIL 16 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 16 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 399.226 KG IN EXPORT ITEM)	1 Number	4	CANDESARTAN CILEXETIL PH.EUR	16.32 mg.
CANDESARTAN CILEXETIL 32 MG TABLETS (EACH UNCOATED TABLET CONTAINS : CANDESARTAN CILEXETIL PH. EUR 32 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 14.400 KG IN EXPORT ITEM)	1 Number	5	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZID E TABLETS 8 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 8 MG AND HYDROCHLOROTHIAZIDE PH.	1 Number	6	CANDESARTAN CILEXETIL PH.EUR	8.16 mg.

EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 2.520 KG IN EXPORT ITEM)				
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 16 MG +12.5 MG (EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 16 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 46.800 KG IN EXPORT ITEM)	1 Number	7	CANDESARTAN CILEXETIL PH.EUR	16.32 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32 MG +12.5 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 12.5 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 11.520 KG IN EXPORT ITEM)	1 Number	8	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.
CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE TABLETS 32 MG +25 MG(EACH UNCOATED TABLET CONTAINS CANDESARTAN CILEXETIL PH. EUR 32 MG AND HYDROCHLOROTHIAZIDE PH. EUR. 25 MG NET CONTENT OF CANDESARTAN CILEXETIL SHOULD NOT BE LESS THAN 11.520 KG IN EXPORT ITEM)	1 Number	9	CANDESARTAN CILEXETIL PH.EUR	32.64 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	117 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred

Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002125AM25
RA File Number	08AX04000637 AM25
Licence No and Date	0811012200/24/07/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	118 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	UNION PARK CHEMICALS BOMBAY PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00002859AM25
RA File Number	03AX04002739 AM25
Licence No and Date	0311036906/05/09/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	119 / NC/3/MEET/Dec/202425/13										
Case Status	Case Approved										
Party Name	POLLOMI PHARMACEUTICAL PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025										
HQ File Number	HQRNORM APPLY 00003074AM25										
RA File Number	52AX04000164 AM25										
Licence No and Date	5211009880/17/09/2024										
Norms Committee Decision:											
Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>PROMESTRIENE 10 MG SOFT GELATINE VAGINAL CAPSULE</td><td>1 Number</td><td>1</td><td>PROMESTRIENE IH API</td><td>10.2 mg/Capsule</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PROMESTRIENE 10 MG SOFT GELATINE VAGINAL CAPSULE	1 Number	1	PROMESTRIENE IH API	10.2 mg/Capsule
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
PROMESTRIENE 10 MG SOFT GELATINE VAGINAL CAPSULE	1 Number	1	PROMESTRIENE IH API	10.2 mg/Capsule							

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

Case No.	120 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00003405AM25
RA File Number	03AX04003124 AM25
Licence No and Date	0311037569/01/10/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Natural Refined Phytosterol 95%	60000 kg.	1	Fatty Acid Distillate /Deoderised Distillate	9,21,250 kg.
		2	Acetone	44,000 kg.
		3	N Heptane	94,050 kg.
Natural Mixed Tocopherol 50%	38500 kg.	4	Fatty Acid Distillate /Deoderised Distillate	9,21,250 kg.
		5	Acetone	44,000 kg.
		6	N Heptane	94,050 kg.

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

Case No.	121 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred

Party Name	SAGA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00003526AM25
RA File Number	08AX04001122 AM25
Licence No and Date	0811012864/08/10/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	122 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	TITAN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00003684AM25
RA File Number	03AX04003549 AM25
Licence No and Date	0311037997/16/10/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	123 / NC/3/MEET/Dec/202425/13
Case Status	Case Deferred
Party Name	PARADISE HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00003965AM25
RA File Number	34AX04000658 AM25
Licence No and Date	3411005628/30/10/2024
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	124 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	SAGA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00004083AM25
RA File Number	08AX04001348 AM25
Licence No and Date	0811013194/12/11/2024
Norms Committee Decision:	

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Dec/202425/12 dated 10/12/2024** against advance authorization **No0811011704 dated 29/05/2024**, 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.
LYSINE CLONIXINATE (125MG) AND PROPINOX HYDROCHLORIDE (10MG) TABLETS (CONTENTS OF LYSINE CLONIXINATE 62.50KGS)	500000 Numbers	1	LYSINE CLONIXINATE	63.75 kg.

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

Case No.	125 / NC/3/MEET/Dec/202425/13
Case Status	Case Approved
Party Name	BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202425/ 13 and 07/01/2025
HQ File Number	HQRNORM APPLY 00004499AM25
RA File Number	03AX04004313 AM25
Licence No and Date	0311039223/02/12/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TAMOXIFEN TABLETS / BP - 20 MG	1 Number	1	TAMOXIFEN CITRATE BP	30.4 mg.

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