



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/May/202526/3

DATED: 04/06/2025

Minutes of the Norms Committee-3 Meeting No.NC/3/MEET/Apr/202526/3 dated 04/06/2025, under the Chairmanship of Shri Rakesh Kumar, Addl. DGFT for considering the cases/issues under Duty Exemption Scheme (Chapter-4) of the Foreign Trade Policy, 2023 pertaining to Chemical and Allied products falling under Chapters 29 and 30.

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

Sl. No.	Name & Designation	Department
1	Shri Dinesh Narain Mathur, Technical Expert	Consultant (Pharma)
2	Shri Shaish Kumar, Technical Expert	Consultant (Chemical)
3	Shri Nand Lal, Technical Expert	Consultant (Chemical)
In attendance:		
1	Shri Raman Kumar, Deputy DGFT	DGFT (HQ)

3. The Norms Committee has taken decisions only with respect to technical aspect / wastage

norms. While redeeming the application, RAs should check that the applicant has fulfilled all requirements as prescribed in policy/procedure, including those in notifications, public notices and policy circulars issued from time to time or any other provisions under FTP/HBP for issuance of Advance Authorization and regularisation of the case.

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

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

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00004369AM25
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:

Sl. No.	Export Product	Qty.
1	CHOLESTYRAMINE FOR ORAL SUSPENSION USP POWDER 4 GRAMS (9 GRAMS POUCH PACK) (EACH POUCH OF 9 GRAMS CONTAIN 4 GRAMS OF CHOLESTYRAMINE RESIN USP) ((ACTIVE INGREDIENT: CHOLESTYRAMINE RESIN USP -NET WT. 30232.800 KGS))	1 Number
2	CHOLESTYRAMINE FOR ORAL SUSPENSION USP POWDER 4 GRAMS (378 GRAMS JAR/BOTTLE PACK) (EACH JAR / BOTTLE OF 378 GRAMS EQUIVALENT TO 42 POUCHES OF 9 GRAMS AND EACH 9 GRAMS CONTAIN 4 GRAMS OF CHOLESTYRAMINE RESIN USP) ((ACTIVE INGREDIENT: CHOLESTYRAMINE RESIN USP - NET WT. 23033.808 KGS))	1 Number
3	CHOLESTYRAMINE FOR ORAL SUSPENSION USP LIGHT POWDER 4 GRAMS (5.5 GRAMS POUCH PACK) (EACH POUCH OF 5.5 GRAMS CONTAIN 4 GRAMS OF CHOLESTYRAMINE RESIN USP) ((ACTIVE INGREDIENT: CHOLESTYRAMINE RESIN USP - NET WT. 21593.520 KGS))	1 Number
4	CHOLESTYRAMINE FOR ORAL SUSPENSION USP LIGHT POWDER 4 GRAMS (231 GRAMS JAR / BOTTLE PACK) (EACH JAR /BOTTLE OF 231 GRAMS EQUIVALENT TO 42 POUCHES OF 5.5 GRAMS AND EACH 5.5 GRAMS CONTAIN 4 GRAMS OF	1 Number

	CHOLESTYRAMINE RESIN USP) ((ACTIVE INGREDIENT: CHOLESTYRAMINE RESIN USP - NET WT. 16797.312 KGS))		
Sl. No.	Import Items	For export of 1 pouch of	
		9 gm	5.5 gm
1	CHOLESTYRAMINE RESIN USP	4.08 gm	4.08 gm
2	SUCROSE NF (COMPRESSUC PS)	4.461 gm	Nil
3	MANNITOL USP (PEARLITOL SD 200)	Nil	1.1575 gm
4	ANHYDROUS CITRIC ACID USP (POWDER GRADE)	0.100 gm	0.060 gm
5	PROPYLENE GLYCOL ALGINATE NF (KELCOLOID S)	0.225 gm	0.050 gm
RA concerned may take further necessary action as per above decision of NC.			

Case No.	2 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00006271AM25
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Sep/202324/14 dated 27/09/2023 against Hq.File No.	

HQRNORMAPPLY00005754AM24 it was decided to fix ad-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

Norms recommended for OMEPRAZOLE DELAYED RELEASE CAPSULE USP 10 mg 20 mg and 40 mg.

Sl.No.	Import Item	10 mg capsule	20 mg capsule	40 mg capsule
1	OMEPRazole USP	10.2 mg	20.4 mg	40.8 mg
2	HYPROMELLOSE 3 CPS 2910 USP	4.68 mg	9.36 mg	18.6 mg
3	HYPROMELLOSE PHTHALATE NF	8.555 mg	17.110 mg	31.0 mg
4	SUGAR SPHERES NF (PHARMA-SPHERES, 710-850 MICRON)	47.50 mg	95.0 mg	190.0 mg
5	TALC PH. E/USP/JP	4.78 mg	9.56 mg	19.12 mg
6	TRIETHYL CITRATE NF	1.285 mg	2.570 mg	4.65 mg

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

Case No.	3 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM REVIW00002300AM25
RA File Number	092404000413 AM12
Licence No and	0910050238/15/12/2011

Date	
Norms Committee Decision: The firm was called for Personal Hearing on 05.06.2025 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for Personal Hearing with relevant documents/information.	

Case No.	4 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	WEXFORD LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM REVIW00003783AM25
RA File Number	072404000382 AM14
Licence No and Date	0710101548/23/01/2014
Norms Committee Decision: The Committee considered the case as per agenda and it has been observed that export product and import item are same. Therefore, it was decided that the firm may call for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents from the firm: I. Copy of Drug Manufacturing Licence (DML) II. Copy of Certificate of Analysis (CoA) of import item. III. Wastage claimed. IV. Copy of Shipping Bill of export product.	

Case No.	5 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	WEXFORD LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM REVIW00003782AM25
RA File Number	072404000120 AM18
Licence No and Date	0710111992/09/08/2017
Norms Committee Decision:	

The Committee considered the case as per agenda and it has been observed that export product and import item are confusing. Therefore, it was decided that the firm may call for attending Personal Hearing before Norms Committee to explain its case along with following information / documents from the firm:

- I. Copy of Drug Manufacturing Licence (DML)
- II. Copy of Certificate of Analysis (CoA) of import item.
- III. Wastage claimed.
- IV. Copy of Shipping Bill of export product.

Case No.	6 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM REVIW00003665AM25
RA File Number	052404000340 AM21
Licence No and Date	0510415463/09/10/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Feb/202425/17 dated 25/02/2025 against advance authorization No. 2910025424 dated 19/08/2019, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dihydromyrcenol	1 kg.	1	Dihydromyrcene (91% Purity)	1.13 kg.

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

Case No.	7 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	KRUNAL INDUSTRIES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025																
HQ File Number	HQRNORM APPLY 00301989AM22																
RA File Number	08AX04000162 AM22																
Licence No and Date	0811003592/30/12/2021																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">2 BROMO 2 NITRO 1,3 PROPANEDIOL (BRONOPOL)</td><td rowspan="2">1 kg.</td><td>1</td><td>NITRO METHANE</td><td>0.3216 Kg</td></tr><tr><td>2</td><td>LIQUID BROMINE</td><td>1.14 Kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	2 BROMO 2 NITRO 1,3 PROPANEDIOL (BRONOPOL)	1 kg.	1	NITRO METHANE	0.3216 Kg	2	LIQUID BROMINE	1.14 Kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
2 BROMO 2 NITRO 1,3 PROPANEDIOL (BRONOPOL)	1 kg.	1	NITRO METHANE	0.3216 Kg													
		2	LIQUID BROMINE	1.14 Kg													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	8 / NC/3/MEET/May/202526/3
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM REVIW00003341AM25
RA File Number	05AX04000760 AM23
Licence No and Date	0511013171/13/06/2022
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	9 / NC/3/MEET/May/202526/3
Case Status	Case Rejected
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM REVIW00006414AM24
RA File Number	09AX04000207 AM23
Licence No and Date	0911003443/05/08/2022
Norms Committee Decision: The Committee considered the 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.	10 / NC/3/MEET/May/202526/3															
Case Status	Case Approved															
Party Name	INTAS PHARMACEUTICALS LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025															
HQ File Number	HQRNORM APPLY 00003389AM23															
RA File Number	08AX04001054 AM23															
Licence No and Date	0811006114/26/09/2022															
Norms Committee Decision:																
The Committee considered the 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>Vardenafil Tablets 5 Mg (Each Film Coated Tablet Contains: Vardenafil (As Vardenafil Hydrochloride Trihydrate Ph.Eur.) 5 Mg)</td><td>540000 Numbers</td><td>1</td><td>Vardenafil Hydrochloride Trihydrate EP / BP / IP / USP / PH. EUR</td><td>3.049 kg</td></tr><tr><td>Vardenafil Tablets 10 Mg (Each Film</td><td>180000</td><td>2</td><td>Vardenafil Hydrochloride</td><td>2.033 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Vardenafil Tablets 5 Mg (Each Film Coated Tablet Contains: Vardenafil (As Vardenafil Hydrochloride Trihydrate Ph.Eur.) 5 Mg)	540000 Numbers	1	Vardenafil Hydrochloride Trihydrate EP / BP / IP / USP / PH. EUR	3.049 kg	Vardenafil Tablets 10 Mg (Each Film	180000	2	Vardenafil Hydrochloride	2.033 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Vardenafil Tablets 5 Mg (Each Film Coated Tablet Contains: Vardenafil (As Vardenafil Hydrochloride Trihydrate Ph.Eur.) 5 Mg)	540000 Numbers	1	Vardenafil Hydrochloride Trihydrate EP / BP / IP / USP / PH. EUR	3.049 kg												
Vardenafil Tablets 10 Mg (Each Film	180000	2	Vardenafil Hydrochloride	2.033 kg												

Coated Tablet Contains: Vardenafil (As Vardenafil Hydrochloride Trihydrate Ph.Eur.) 10 Mg)	Numbers		Trihydrate EP / BP / IP / USP / PH. EUR.	
Vardenafiltablets 20mg (Each Film Coated Tablet Contains: Vardenafil (As Vardenafil Hydrochloride Trihydrate Ph.Eur.) 20 Mg [In Which Active Ingredient Vardenafil Hydrochloride Trihydrate Used Is 5.520 Kgs.])	51000 Numbers	3	Vardenafil Hydrochloride Trihydrate EP / BP / IP / USP / PH. EUR	1.162 kg

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

Case No.	11 / NC/3/MEET/May/202526/3			
Case Status	Case Approved			
Party Name	NECTAR LIFE SCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025			
HQ File Number	HQRNORM APPLY 00003987AM23			
RA File Number	302404000100 AM20			
Licence No and Date	3011002766/01/11/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 3011005168 dated 13/05/2024, 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.
Ceftibuten Hydrate	1 kg	1	GHYH	2.977 kg.
		2	Ethyl-4-chloroacetoacetate	1.82 kg.

		3	Methylene Chloride	85.60 kg.
		4	Triethylamine	3.214 kg
		5	Isopropyl acetate	7.99 kg.
		6	DL Malic acid	7.18 kg.
		7	Methanol	52.50 kg.
		8	Prenol (Prenyl alcohol)	3.114 kg.
		9	Methyl 3-methoxyacrylate	1.62 kg.
		10	Dimethylformamide (DMF)	4.82 kg.
		11	Toluene	0.38 kg.
		12	Acetone	2.13 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	12 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00004409AM23
RA File Number	03AX04003954 AM23
Licence No and Date	0311019281/17/11/2022
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.
Secnidazole Taste Masked Pellets	1 kg	1	Secnidazole IH	0.478 kg

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

Case No.	13 / NC/3/MEET/May/202526/3													
Case Status	Case Approved													
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025													
HQ File Number	HQRNORM APPLY 00004437AM23													
RA File Number	03AX04003955 AM23													
Licence No and Date	0311019320/18/11/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Secnidazole Taste Masked Pellets</td><td>1 kg</td><td>1</td><td>Secnidazole IH</td><td>0.478 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Secnidazole Taste Masked Pellets	1 kg	1	Secnidazole IH	0.478 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Secnidazole Taste Masked Pellets	1 kg	1	Secnidazole IH	0.478 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	14 / NC/3/MEET/May/202526/3			
Case Status	Case Deferred			
Party Name	SCL LIFESCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025			

HQ File Number	HQRNORM APPLY 00006594AM23
RA File Number	30AX04000547 AM23
Licence No and Date	3011003202/24/02/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	15 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	MAHARASHTRA ALDEHYDES AND CHEMICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00006735AM23
RA File Number	03AX04004601 AM23
Licence No and Date	0311021876/03/03/2023
Norms Committee Decision:	
The Committee considered the case and firm is requested to amend the export item as Triethyl Citate and furnish the copy of the amended authorization.	

Case No.	16 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM REVIW00006563AM24
RA File Number	08AX04001977 AM23
Licence No and Date	0811007532/10/03/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	17 / NC/3/MEET/May/202526/3
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Case Status	Case Approved										
Party Name	S KANT CHEMICALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025										
HQ File Number	HQRNORM APPLY 00000218AM24										
RA File Number	03AX04000033 AM24										
Licence No and Date	0311022832/17/04/2023										
Norms Committee Decision:											
The Committee considered the 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>9,11 B - Expoxide Triamcinolone (5TR)</td><td>1 kg</td><td>1</td><td>3,20-Dioxopregna-1,4,9 (11),16-Tetraen-21-Yl Acetate (3tr)</td><td>1.05 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	9,11 B - Expoxide Triamcinolone (5TR)	1 kg	1	3,20-Dioxopregna-1,4,9 (11),16-Tetraen-21-Yl Acetate (3tr)	1.05 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
9,11 B - Expoxide Triamcinolone (5TR)	1 kg	1	3,20-Dioxopregna-1,4,9 (11),16-Tetraen-21-Yl Acetate (3tr)	1.05 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	18 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000292AM24
RA File Number	03AX04000045 AM24
Licence No and Date	0311022935/19/04/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No. 0311029682 dated 27/12/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tylosin Bolus 200 mg. ((Each Bolus Contains Tylosin 200mg)	1 Number	1	Tylosin Tartrate	204.00 mg.
Tylosin Injection 5% - 50 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin Base 50mg)	1 Number	2	Tylosin Tartrate	3.056 gm.
Tylosin Injection 5% - 100 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin Base 50mg)	1 Number	3	Tylosin Tartrate	6.111 gm.
Tylosin Tartrate Injection 20% - 50 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin 200mg)	1 Number	4	Tylosin Tartrate	12.222 gm.
Tylosin Tartrate Injection 20%-100 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin 200mg)	1 Number	5	Tylosin Tartrate	24.444 gm.
Tylosin Tartrate Powder 100% -100 gm. Sachet ((Each Gram Contains Tylosin Tartrate 100%)	1 Number	6	Tylosin Tartrate	101 gm.
Tylosin Tartrate Powder 100% - 500 gm. Sachet ((Each Gram Contains Tylosin Tartrate 100%)	1 Number	7	Tylosin Tartrate	505 gm.
Tylosin Tartrate Powder 100% -1 kg Jar ((Each Gram Contains Tylosin Tartrate 100%)	1 Number	8	Tylosin Tartrate	1010 gm.
Tylosin Tartrate Powder 20% -5 gm. ((Each Gram Contains Tylosin Tartrate Eq. To Tylosin 20%)	1 Number	9	Tylosin Tartrate	1.1756 gm.
Tylosin Tartrate Powder 20% -100 gm. ((Each Gram Contains Tylosin	1 Number	10	Tylosin Tartrate	23.513 gm.

Tartrate Eq. To Tylosin 20%)				
Tylosin Tartrate Powder 20% - 500 gm. ((Each Gram Contains Tylosin Tartrate Eq. To Tylosin 20%))	1 Number	11	Tylosin Tartrate	117.564 gm.
Tylosin Tartrate Powder 20% -1kg Jar ((Each Gram Contains Tylosin Tartrate Eq. To Tylosin 20%))	1 Number	12	Tylosin Tartrate	235.128 gm.
Tylosin Tartrate Powder 99% - 100 gm Sachet ((Each Gram Contains Tylosin Tartrate 99%))	1 Number	13	Tylosin Tartrate	100 gm.
Tylosin Tartrate Powder 99% - 500 gm Sachet ((Each Gram Contains Tylosin Tartrate 99%))	1 Number	14	Tylosin Tartrate	500 gm.
Tylosin Tartrate Powder 99% -1 kg Jar ((Each Gram Contains Tylosin Tartrate 99%))	1 Number	15	Tylosin Tartrate	1000 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	19 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000325AM24
RA File Number	03AX04000169 AM24
Licence No and Date	0311022998/21/04/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance	

authorization No. 0311029682 dated 27/12/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tylosin Bolus 200 mg. ((Each Bolus Contains Tylosin 200 Mg)	1 Number	1	Tylosin Tartrate	204.00 mg.
Tylosin Injection 5% - 50 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin Base 50 mg.)	1 Number	2	Tylosin Tartrate	3.056 gm.
Tylosin Injection 5% - 100 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin Base 50 mg)	1 Number	3	Tylosin Tartrate	6.111 gm.
Tylosin Tartrate Injection 20% - 50 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin 200mg)	1 Number	4	Tylosin Tartrate	12.222 gm.
Tylosin Tartrate Injection 20% - 100 ml. ((Each Ml Contains Tylosin Tartrate Eq. To Tylosin 200 Mg)	1 Number	5	Tylosin Tartrate	24.444 gm.
Tylosin Tartrate Powder 100% - 100 gm. Sachet ((Each Gram Contains Tylosin Tartrate 100%)	1 Number	6	Tylosin Tartrate	101 gm.
Tylosin Tartrate Powder 100% - 500 gm. Sachet ((Each Gram Contains Tylosin Tartrate 100%)	1 Number	7	Tylosin Tartrate	505 gm.
Tylosin Tartrate Powder 100% - 1 kg. Jar ((Each Gram Contains Tylosin Tartrate 100%)	1 Number	8	Tylosin Tartrate	1010 gm.
Tylosin Tartrate Powder 20% - 5 gm. ((Each Gram Contains Tylosin Tartrate Eq. To Tylosin 20%)	1 Number	9	Tylosin Tartrate	1.1756 gm.

Tylosin Tartrate Powder 20% -100 gm. ((Each Gram Contains Tylosin Tartrate Eq. To Tylosin 20%))	1 Number	10	Tylosin Tartrate	23.513 gm.
Tylosin Tartrate Powder 20% -500 gm. ((Each Gram Contains Tylosin Tartrate Eq. To Tylosin 20%))	1 Number	11	Tylosin Tartrate	117.564 gm.
Tylosin Tartrate Powder 20% - 1 kg. Jar ((Each Gram Contains Tylosin Tartrate Eq. To Tylosin 20%))	1 Number	12	Tylosin Tartrate	235.128 gm.
Tylosin Tartrate Powder 99% - 100 gm. Sachet ((Each Gram Contains Tylosin Tartrate 99%))	1 Number	13	Tylosin Tartrate	100 gm.
Tylosin Tartrate Powder 99% - 500 gm. Sachet ((Each Gram Contains Tylosin Tartrate 99%))	1 Number	14	Tylosin Tartrate	500 gm.
Tylosin Tartrate Powder 99% - 1 kg Jar ((Each Gram Contains Tylosin Tartrate 99%))	1 Number	15	Tylosin Tartrate	1000 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	20 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	SATYADEVA PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000775AM24
RA File Number	09AX04000090 AM24
Licence No and Date	0911005025/11/05/2023
Norms Committee Decision:	

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

1. Percentage on molar basis as per the present data of production.
2. Production/consumption data for the last three years certified by Chartered Accountant.

Case No.	21 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000897AM24
RA File Number	05AX04000410 AM24
Licence No and Date	0511018871/17/05/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202425/2 dated 30/04/2024 against advance authorization No. 0511019270 dated 09/06/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Kombinil-DUO Eye/Ear Drops 5ml Vial	925926 Vials	1	Dexamethasone Micronised PH EUR USP JP	4.72 kg

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

Case No.	22 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025

HQ File Number	HQRNORM APPLY 00000920AM24
RA File Number	08AX04000086 AM24
Licence No and Date	0811008233/18/05/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PREGABALIN CAPSULES 25 MG (EACH HARD GELATIN CAPSULES CONTAINS: PREGABALIN 25 MG)	1 Number	1	PREGABALIN EP / BP / IP / USP / PH. EUR.	25.50 mg
			HARD GELATIN CAPSULE	Relevant, As per packing policy and General Notes.
PREGABALIN CAPSULES 50 MG (EACH HARD GELATIN CAPSULES CONTAINS: PREGABALIN 50 MG)	1 Number	2	PREGABALIN EP / BP / IP / USP / PH. EUR	51.00 mg
			HARD GELATIN CAPSULE	Relevant, As per packing policy and General Notes.
PREGABALIN CAPSULES 75 MG (EACH HARD GELATIN CAPSULES CONTAINS: PREGABALIN 75 MG)	1 Number	3	PREGABALIN EP / BP / IP / USP / PH. EUR.	76.5 mg
			HARD GELATIN	Relevant, As per packing policy and General Notes.

PREGABALIN CAPSULES 100 MG (EACH HARD GELATIN CAPSULES CONTAINS: PREGABALIN 100 MG)	1 Number	4	PREGABALIN EP / BP / IP / USP / PH. EUR .	102.00 mg
			HARD GELATIN CAPSULE	Relevant, As per packing policy and General Notes.
PREGABALIN CAPSULES 150 MG (EACH HARD GELATIN CAPSULES CONTAINS: PREGABALIN 150 MG)	1 Number	5	PREGABALIN EP / BP / IP / USP / PH. EUR.	153.00 mg
			HARD GELATIN CAPSULE	Relevant, As per packing policy and General Notes.
PREGABALIN CAPSULES 200 MG (EACH HARD GELATIN CAPSULES CONTAINS: PREGABALIN 200 MG)	1 Number	6	PREGABALIN EP / BP / IP / USP / PH. EUR.	204.00 mg
			HARD GELATIN CAPSULE	Relevant, As per packing policy and General Notes.
PREGABALIN CAPSULES 225 MG (EACH HARD GELATIN CAPSULES CONTAINS: PREGABALIN 225 MG)	1 Number	7	PREGABALIN EP / BP / IP / USP / PH. EUR.	229.50 mg
			HARD GELATIN CAPSULE	Relevant, As per packing policy and General Notes.

PREGABALIN CAPSULES 300 MG (EACH HARD GELATIN CAPSULES CONTAINS: PREGABALIN 300 MG [IN WHICH ACTIVE INGREDIENT PREGABALIN USED IS 3450.000 KGS.])	1 Number	8	PREGABALIN EP / BP / IP / USP / PH. EUR.	306.00 mg
			HARD GELATIN CAPSULE	Relevant, As per packing policy and General Notes.

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

Case No.	23 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	HINDYS LAB PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001037AM24
RA File Number	09AX04001157 AM23
Licence No and Date	0911005091/23/05/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Diloxanide furoate, Cimetidine, Oxylozanide, Famotidine: Other (Tert-Butyl-2-((4R,6S)-6-((E)-2-(4-(4-Fluorophenyl)-6- Isopropyl-2-(N-Methyl methane sulfonamido) Pyrimidin-5-Yl) vinyl)-2,2-Dimethyl-1,3-Dioxane-4-Yl-) Acetate)	1 kg	1	Tertiarybutyl-[2-((4R,6S)-6-(Acetyloxy) Methyl-2,2-Dimethyl-1,3-Dioxane-4-yl] Acetate(Heterocyclic Compounds With Nitrogen Hetero-atom(s)	1.136 kg
		2	N-[5-(bromomethyl)-4-(4-	1.44 kg

			fluorophenyl)-6-isopropyl pyrimidin-2-yl]-N-methyl methane sulphonamide (Salts of formic acid: Other)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	24 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	AGRO SOLVENT PRODUCTS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001107AM24
RA File Number	56AX04000449 AM23
Licence No and Date	5611001909/25/05/2023
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	25 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	INTIGREAT CONSULTING SERVICES LLP
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001324AM24
RA File Number	03AX04000737 AM24
Licence No and Date	0311024265/06/06/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/2 dated 08/05/2025 against advance authorization No. 0311017790 dated 12/09/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tablets / Capsules(REMURES ULTRA (Diosmin 450 mg + Hesperidine 50 mg) coated tablets Pack 2 x 15 tablets = 30 Tablets in one Pack, (NET CONTENT = 225.00 KGS),TOTAL GROSS CONTENT (MFG OVERAGES 5% + 2% MFG LOSS) = 240.75 KGS)	1 Number	1	Diosmin/Hesperidine (90/10)	510 mg.
Tablets / Capsules(REMURES ULTRA (Diosmin 450 mg + Hesperidine 50 mg) coated tablets Pack 4 x 15 tablets = 60 Tablets in one Pack. (NET CONTENT = 255.00 KGS) ,TOTAL GROSS CONTENT (MFG OVERAGES 5% + 2% MFG LOSS) = 272.85 KGS)	1 Number	2	Diosmin/Hesperidine (90/10)	510 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	26 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	SHILPA PHARMA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001330AM24
RA File Number	07AX04000315 AM24
Licence No and Date	0711007735/06/06/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Gemcitabine HCL	1 kg	1	2 Deoxy 2 2 Difluoro D Erythro Pentafuranous 1 Ulose 3 5 Dibenzoate	4.78 kg
		2	Tetra Hydro Furan	4.60 kg
		3	Methylene Dichloride	6.20 kg
		4	N Acetyl Cytosine	2.92 kg
		5	Trimethyl Silyl Trifluoromethane Sulfonate	4.23 kg
		6	Methanol	6.20 kg

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

Case No.	27 / NC/3/MEET/May/202526/3
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM REVIW00003342AM25
RA File Number	05AX04001798 AM24
Licence No and Date	0511021104/22/09/2023
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	28 / NC/3/MEET/May/202526/3
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM REVIW00003344AM25
RA File Number	05AX04002118 AM24
Licence No and Date	0511021548/16/10/2023
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	29 / NC/3/MEET/May/202526/3
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM REVIW00003345AM25
RA File Number	05AX04003290 AM24
Licence No and Date	0511023265/15/01/2024
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	30 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	PRASOL CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00008287AM24
RA File Number	03AX04004987 AM24

Licence No and Date	0311030614/01/02/2024
Norms Committee Decision: The committee considered the request of the firm for fixation of ad-hoc norms, and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Percentage Yield of reaction not given. 2. Quantity and value of by-product MPD	

Case No.	31 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	YELLOWSTONE FINE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
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 the 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 of 55% Yield.	

Case No.	32 / NC/3/MEET/May/202526/3
Case Status	Case Rejected
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM REVIW00003346AM25
RA File Number	05AX04003839 AM24
Licence No and Date	0511024393/07/03/2024
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	33 / NC/3/MEET/May/202526/3										
Case Status	Case Approved										
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025										
HQ File Number	HQRNORM APPLY 00009209AM24										
RA File Number	03AX04005812 AM24										
Licence No and Date	0311032330/19/03/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Ferrous Fumarate USP/BP/FCC/IP</td><td>1 kg</td><td>1</td><td>Fumaric Acid 99 %</td><td>0.725 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ferrous Fumarate USP/BP/FCC/IP	1 kg	1	Fumaric Acid 99 %	0.725 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Ferrous Fumarate USP/BP/FCC/IP	1 kg	1	Fumaric Acid 99 %	0.725 kg							
Note: NC also decided to make a new SION on the above export product.											
RA concerned may take further necessary action as per above decision of NC.											

Case No.	34 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00009219AM24
RA File Number	03AX04005814 AM24
Licence No and Date	0311032351/20/03/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ferrous Fumarate USP/BP/FCC/IP	1 kg	1	Maleic Anhydride	0.65 kg

Note: NC also decided to make a new SION on the above export product.

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

Case No.	35 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00009247AM24
RA File Number	03AX04005861 AM24
Licence No and Date	0311032405/21/03/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/May/202425/4 dated 06.06.2024 against advance authorization No . 0311016913 dated 05.08.2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxycycline Hyclate DR Tablets USP 200 mg 60 S((2,333 Bottles X 60 Per Bottles = 1,39,980 Tablets) (Total Weight of Export Product = 27.996 Kgs) (Net Content weight of Import Product = 38.290 kgs))	1 Number	1	Doxycycline Hyclate	230.80 mg.
Doxycycline Hyclate DR Tablets USP 100 mg , 100 S US ((9,900 Bottles X 100 Per Bottles = 9,90,000 Tablets) (Total Weight of Export Product = 99.000 Kgs) (Net Content weight of Import Product =	1 Number	2	Doxycycline Hyclate	115.40 mg.

135.402 kgs))

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

Case No.	36 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	GALAXY SURFACTANTS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00009329AM24
RA File Number	03AX04005978 AM24
Licence No and Date	0311032511/26/03/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Aug/202425/8 dated 28.08.2024 against advance authorization No. 0311032511 dated 26.03.2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Phenoxyethanol	1 kg	1	Phenol	0.690 kg.
		2	Ethylene Oxide	0.325 kg.

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

Case No.	37 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00009338AM24

RA File Number	08AX04002294 AM24			
Licence No and Date	0811011115/27/03/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No. 0811011004 dated 13/03/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Magnesium Sulfate In Water for Injection (0.325 m Eq Mg++/mL) 40 mg/mL 2g Total	1 Number	1	Magnesium Sulfate Heptahydrate Ph Eur	2.00 gm.
Magnesium Sulfate In Water for Injection (0.325 m Eq Mg++/mL) 40 mg/mL 4g Total	1 Number	2	Magnesium Sulfate Heptahydrate Ph Eur	4.00 gm.

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

Case No.	38 / NC/3/MEET/May/202526/3			
Case Status	Case Approved			
Party Name	GALAXY SURFACTANTS LTD			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025			
HQ File Number	HQRNORM APPLY 00009360AM24			
RA File Number	03AX04006006 AM24			
Licence No and Date	0311032575/27/03/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Sodium Lauroyl Methyl Taurate (Galsoft SLT (N) / Galsoft SLT (N) MB)	1 kg.	1	Lauric Acid	0.614 kg
		2	N-Methyl Taurine Sodium Salt 62%.	0.728 kg

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

Case No.	39 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000028AM25
RA File Number	30AX04000590 AM24
Licence No and Date	3011005003/02/04/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sugammadex solution for Injection 100 mg / ml (200 mg / 2 ml) (Each vial of 2ml contains: Sugammadex Sodium equivalent to sugammadex 200 mg Hydrochloric acid 3.7% (to adjust pH) and /or Sodium hydroxide (to adjust pH) Water for Injections..... q.s Containing 4.000 Kg of Sugammadex Sodium)	1 Number	1	Sugammadex Sodium	239.326 mg

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

Case No.	40 / NC/3/MEET/May/202526/3																
Case Status	Case Approved																
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025																
HQ File Number	HQRNORM APPLY 00000065AM25																
RA File Number	09AX04001116 AM24																
Licence No and Date	0911007027/03/04/2024																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<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">Atinvecitinib (or) 1-[(3R,4S)-4-Cyanotetrahydropyran-3-yl]-3-[(2-fluoro-6-methoxy-4-pyridyl)amino]pyrazole-4-Carboxamid ((L-005251026-Form-I))</td><td rowspan="2">1 kg</td><td>1</td><td>2-Fluoro-6-methoxy pyridine (FMP)</td><td>1.975 kg</td></tr><tr><td>2</td><td>4,5-bis (Diphenylphosphino)-9,9-dimethylxanthane (Xantphos)</td><td>0.125 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Atinvecitinib (or) 1-[(3R,4S)-4-Cyanotetrahydropyran-3-yl]-3-[(2-fluoro-6-methoxy-4-pyridyl)amino]pyrazole-4-Carboxamid ((L-005251026-Form-I))	1 kg	1	2-Fluoro-6-methoxy pyridine (FMP)	1.975 kg	2	4,5-bis (Diphenylphosphino)-9,9-dimethylxanthane (Xantphos)	0.125 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Atinvecitinib (or) 1-[(3R,4S)-4-Cyanotetrahydropyran-3-yl]-3-[(2-fluoro-6-methoxy-4-pyridyl)amino]pyrazole-4-Carboxamid ((L-005251026-Form-I))	1 kg	1	2-Fluoro-6-methoxy pyridine (FMP)	1.975 kg													
		2	4,5-bis (Diphenylphosphino)-9,9-dimethylxanthane (Xantphos)	0.125 kg													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	41 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	PLASTIBLENDS INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000067AM25
RA File Number	03AX04006127 AM24
Licence No and Date	0311032797/03/04/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Additive Masterbatch (ITC(HS) Code 29420090) NET CONTENT:1) Relevant polymer such as Hydrocarbon Resin: 86625.00KGS(2) Additive namely Antioxidant: 173.250KGS 3) Relevant polymers such as BOPP:86451.750 KGS)	173250 kg.	1	Relevant polymer such as Hydrocarbon Resin	89223.75 kg.
		2	Additive namely Antioxidant	178.448 kg.
		3	Hompopolymer of PP	89045 kg.

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

Case No.	42 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	LIVMORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000105AM25
RA File Number	34AX04000777 AM24
Licence No and Date	3411004764/05/04/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Bulk Drug (Levetiracetam IH/USP/BP/EP (Net Content Of Input In Export Product Is 2000 Kgs.))	1 kg	1	SABAM HCL (S-(+)-2- AMINO BUTYRAMIDE HYDROCHLORIDE (SABAM HCL) CAS	0.95 kg

			NO.7682-20-4)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	43 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	LIVMORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000106AM25
RA File Number	34AX04000776 AM24
Licence No and Date	3411004765/05/04/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Rosuvastatine Calcium IH/USP/BP/EP (Rosuvastatin Calcium Monohydrate IH/USP/BP/EP (Net Content of Input In Export Product is 1000 Kgs))	1 kg	1	Bulk Drug Intermediates (Tert- Butyl 6-[(1e)-2-[4-(4- Fluoromethyl)-6(1-Methyl (Methyl (Methylsulphonyl Amino)-5-Pyrimidinyl) Ethenyl) 2-2-Dimethyl- 1,3-dioxane]casno.289042-12-2)	1.30 kg

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

Case No.	44 / NC/3/MEET/May/202526/3
Case Status	Case Approved

Party Name	UMEDICA LABORATORIES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025													
HQ File Number	HQRNORM APPLY 00000145AM25													
RA File Number	03AX04000009 AM25													
Licence No and Date	0311032889/08/04/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<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>Rosuvastatin Tablet BP/ USP 10 MG. ((Each Tablet contains Rosuvastatin Calcium 10.400 mg) Eq. to Rosuvastatin 10 mg. (Net wt of import material is 490.474 kg.))</td><td>1 Number</td><td>1</td><td>Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl) acetate</td><td>10.608 mg/Tablet</td></tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Rosuvastatin Tablet BP/ USP 10 MG. ((Each Tablet contains Rosuvastatin Calcium 10.400 mg) Eq. to Rosuvastatin 10 mg. (Net wt of import material is 490.474 kg.))	1 Number	1	Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl) acetate	10.608 mg/Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Rosuvastatin Tablet BP/ USP 10 MG. ((Each Tablet contains Rosuvastatin Calcium 10.400 mg) Eq. to Rosuvastatin 10 mg. (Net wt of import material is 490.474 kg.))	1 Number	1	Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl) acetate	10.608 mg/Tablet										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	45 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	VINCIT LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000334AM25
RA File Number	05AX04004078 AM24
Licence No and Date	0511025080/19/04/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No. 0311031186 dated 14/02/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Levofloxacin Hemihydrate	1 kg	1	Levofloxacin Q Acid Or Levofloxacin Carboxylic Acid)	0.856 kg.
		2	N Methyl Piperazine	0.432 kg.

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

Case No.	46 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000476AM25
RA File Number	08AX04000132 AM25
Licence No and Date	0811011403/29/04/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Dec/202425/12 dated 10/12/2024 against advance authorization No. 0811011676 dated 28/05/2024, 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.
Sitagliptin Free Base	1 kg	1	(R)-3-[(tert-butoxycarbonyl) amino-4-(2,4,5-trifluorophenyl)] butanoic acid	0.953 kg.
		2	3-(trifluoromethyl)-5,6,7,8-tetrahydro [1,2,4] triazolo [4,3-a] pyrazine hydrochloride	0.686 kg.

		3	O-(Benzotriazol-1-yl)-N,N,N',N'-tetramethyluronium	0.936 kg.
		4	Isopropyl Alcohol (Solvent))	6.80 kg.
		5	Methanol	5.25 kg.

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

Case No.	47 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000737AM25
RA File Number	34AX04000120 AM25
Licence No and Date	3411004931/15/05/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No. 3411005383 dated 09/09/2024, 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.
Aldehyde C10 (Capric Aldehyde)	1 kg.	1	Fatty Alcohol C10 (98% Purity)	1.40 kg.

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

Case No.	48 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	APTRA SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00000952AM25
RA File Number	26AX04000006 AM25
Licence No and Date	2611001464/28/05/2024
Norms Committee Decision: The firm was called for Personal Hearing on 05.06.2025 through Video Conference, but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for <u>Personal Hearing</u> with relevant documents/information	

Case No.	49 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	AARTI PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001028AM25
RA File Number	03AX04000079 AM25
Licence No and Date	0311034279/31/05/2024
Norms Committee Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	50 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	CLARIANT INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001120AM25
RA File Number	03AX04001111 AM25
Licence No and	0311034385/05/06/2024

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Piroctone Olamine Or Vipirox (Octopirox Plus)	1 kg	1	Dimethyl Acrylic Acid Ester	0.770 kg
		2	Hydroxyl ammonium sulfate	1.628 kg
		3	Isononyl Acid Chloride	1.515 kg
		4	Mono Ethanol Amine	0.372 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	51 / NC/3/MEET/May/202526/3			
Case Status	Case Approved			
Party Name	MOREPEN LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025			
HQ File Number	HQRNORM APPLY 00001122AM25			
RA File Number	05AX04000723 AM25			
Licence No and Date	0511025891/05/06/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Dapagliflozin Amorphous	1 kg	1	5-Bromo-2-Chloro-4'-ethoxydiphenylmethane (DP01)	1.233 kg
		2	2,3,4,6-Tetra-O-trimethylsilyl-B-D-glucolactone (DPS01) or 2,3,4,6-Tetrakis-O-trimethylsilyl-D-gluconolactone (DPS01)	2.120 kg
		3	(S)-(+)-1,2-Propanediol	0.200 kg
		4	Acetonitrile	3.16 kg
		5	Tetrahydrofuran	3.80 kg
		6	N,N Diisopropyl ethyl amine	3.667 kg

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

Case No.	52 / NC/3/MEET/May/202526/3			
Case Status	Case Approved			
Party Name	MOREPEN LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025			
HQ File Number	HQRNORM APPLY 00001123AM25			
RA File Number	05AX04000722 AM25			
Licence No and Date	0511025892/05/06/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Dapagliflozin Amorphous	1 kg	1	5-Bromo-2-Chloro-4'-ethoxydiphenylmethane (DP01)	1.233 kg
		2	2,3,4,6-Tetra-O-trimethylsilyl-B-D-glucolactone (DPS01) or 2,3,4,6-Tetrakis-O-trimethylsilyl-D-gluconolactone (DPS01)	2.120 kg
		3	(S)-(+)-1,2-Propanediol	0.200 kg
		4	Acetonitrile	3.16 kg
		5	Tetrahydrofuran	3.80 kg
		6	N,N Diisopropyl ethyl amine	3.667 kg

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

Case No.	53 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001242AM25
RA File Number	05AX04000783 AM25
Licence No and Date	0511026035/11/06/2024
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No. 0511023848 dated 08/02/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tri Ethyl Citrate (Tec) (Packed In 2,000 Nos. of Hm-HDPE Drums Made of Hdpe Granules (17,000.000 Kgs. Without Wastage)) (Each Drum Shall Weight 8.5 Kg and Storage Capacity 250.000 Kgs.))	1 kg	1	Citric Acid	0.726 kg.
		2	Denatured Ethyl Alcohol	0.526 kg.
		3	HDPE Granules (Total Weight = 17,850.000 Kgs.)	Relevant, as per packing policy and General Notes.

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

Case No.	54 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	ALCHEMIE FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001248AM25
RA File Number	03AX04001154 AM25
Licence No and Date	0311034547/12/06/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
N Ethyl N Benzyl Aniline Sulphonic Acid (N,Ethyl-N-(3 Sulfobenzyl Aniline	1 kg	1	Aniline	0.533 kg
		2	Benzyl Chloride	0.621 kg
		3	Caustic Soda Lye	0.196 kg

		4	Ethyl Alcohol and other Spirits Denatured of any Strength Denatured Ethyl Alcohol	0.260 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	55 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001292AM25
RA File Number	03AX04001135 AM25
Licence No and Date	0311034573/13/06/2024
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 sample of exort product/import item from the firm.	

Case No.	56 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001293AM25
RA File Number	03AX04001186 AM25
Licence No and Date	0311034574/13/06/2024
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 sample of exort product/import item from the firm.	

Case No.	57 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	LINCOLN PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001296AM25
RA File Number	08AX04000313 AM25
Licence No and Date	0811011811/13/06/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Nov/202425/10 dated 22/11/2024 against advance authorization No. 0811007126 dated 31/01/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Alendronate Sodium Tablets Usp 70 Mg (Packing 1x4 = 4 Nos In Each Pack.) ((Total Sodium Alendronate Trihydrate Used I.E. 400000 X 91.37 / 1000000= 36.55 Kg Net))	1 Number Tablet	1	Sodium Alendronate Trihydrate ((This License Issued In Terms Of P.C No:9(Re-2003)2002- 2007dt: 30.6.03.License will comply with all conditions of the said circular read with conditions mentioned in P.C.No:15(RE-2003)2002-2007dt:17.9.03))	93.197 mg.

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

Case No.	58 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001309AM25

RA File Number	03AX04001212 AM25
Licence No and Date	0311034498/13/06/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0311036028 dated 05/08/2024, 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.
Alclox-250 Capsule . Cloxacillin Sodium Capsules USP 250mg. ((Each Capsule Containing Cloxacillin Sodium BP Equivalent To 250mg of Cloxacillin)	1069377 Numbers	1	Cloxacillin Sodium BP Compacted	297.22 kg.
Alclox-500 Capsule . Cloxacillin Sodium Capsules USP 500 mg. ((Each Capsule Containing Cloxacillinsodium BP Equivalent To 500 mg of cloxacillin).	3256772 Numbers	2	Cloxacillin Sodium BP Compacted	1810.43 kg.
Ampicillin and Cloxacillin Capsules (250 mg +250 mg) (Each capsule contains Ampicillin Trihydrate equivalent to 250mg (Lampyklox Capsule. Cloxacillin Cap (250 mg+250 mg) (Each Cap Containing Cloxacillin sodium Equi to 250 Mg of Cloxacillin)	3000000 Numbers	3	Cloxacillin Sodium BP Compacted	833.85 kg.
Alclox -125 Syrup. Cloxacillin Socium for Oral Solution USP ((Each 5 Ml Contains Cloxacillin sodium BP Equivalent To 125 Mg Of Cloxacillin	21000 Numbers	4	Cloxacillin Sodium BP Compacted	58.48 kg.

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

Case No.	59 / NC/3/MEET/May/202526/3																
Case Status	Case Approved																
Party Name	CHEMPLAST SANMAR LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025																
HQ File Number	HQRNORM APPLY 00001314AM25																
RA File Number	04AX04000189 AM25																
Licence No and Date	0411007575/13/06/2024																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202425/18 dated 17/03/2025 against advance authorization No. 0411007898 dated 26/07/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td rowspan="2">(4R)-2-oxooxazolidine-4-carboxylic acid (COX)((4R)-2-oxooxazolidine-4-carboxylic acid (COX))</td><td rowspan="2">1 kg</td><td>1</td><td>D-Serine ((R)-2-amino-3-hydroxypropanoic acid</td><td>1.073 kg.</td></tr><tr><td>2</td><td>Potassium methoxide 32% in methanol</td><td>2.240 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	(4R)-2-oxooxazolidine-4-carboxylic acid (COX)((4R)-2-oxooxazolidine-4-carboxylic acid (COX))	1 kg	1	D-Serine ((R)-2-amino-3-hydroxypropanoic acid	1.073 kg.	2	Potassium methoxide 32% in methanol	2.240 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
(4R)-2-oxooxazolidine-4-carboxylic acid (COX)((4R)-2-oxooxazolidine-4-carboxylic acid (COX))	1 kg	1	D-Serine ((R)-2-amino-3-hydroxypropanoic acid	1.073 kg.													
		2	Potassium methoxide 32% in methanol	2.240 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	60 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001396AM25
RA File Number	09AX04000130 AM25
Licence No and Date	0911007445/18/06/2024
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sotagliflozin	1 kg	1	4-chloro-ethoxybenzyl hydroxy methanone	1.70 kg

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

Case No.	61 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	STERIL-GENE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001488AM25
RA File Number	04AX04001003 AM24
Licence No and Date	0411007616/21/06/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Dec/202425/13 dated 07/01/2025 against advance authorization No. 0311039223 dated 02/12/2024, 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.
Tamoxifen 20 Mg Tablets	1 Number	1	Tamoxifen Citrate	30.4 mg.

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

Case No.	62 / NC/3/MEET/May/202526/3
Case Status	Case Rejected

Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001489AM25
RA File Number	03AX04001452 AM25
Licence No and Date	0311034818/21/06/2024
Norms Committee Decision: The firm was called for Personal Hearing on 05/06/2025 through Video Conference, but the firm could not appear before Norms Committee. Hence, it was decided to reject the application of the firm.	

Case No.	63 / NC/3/MEET/May/202526/3
Case Status	Case Rejected
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001490AM25
RA File Number	03AX04001450 AM25
Licence No and Date	0311034819/21/06/2024
Norms Committee Decision: The firm was called for Personal Hearing on 05/06/2025 through Video Conference, but the firm could not appear before Norms Committee. Hence, it was decided to reject the application of the firm.	

Case No.	64 / NC/3/MEET/May/202526/3
Case Status	Case Rejected
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001491AM25
RA File Number	03AX04001449 AM25
Licence No and Date	0311034820/21/06/2024
Norms Committee Decision: The firm was called for Personal Hearing on 05/06/2025 through Video Conference, but the firm could not appear before Norms Committee. Hence, it was decided to reject the application of the firm.	

Case No.	65 / NC/3/MEET/May/202526/3
Case Status	Case Rejected
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001493AM25
RA File Number	03AX04001447 AM25
Licence No and Date	0311034821/21/06/2024
Norms Committee Decision: The firm was called for Personal Hearing on 05/06/2025 through Video Conference, but the firm could not appear before Norms Committee. Hence, it was decided to reject the application of the firm.	

Case No.	66 / NC/3/MEET/May/202526/3
Case Status	Case Rejected
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001494AM25
RA File Number	03AX04001441 AM25
Licence No and Date	0311034822/21/06/2024
Norms Committee Decision: The firm was called for Personal Hearing on 05/06/2025 through Video Conference, but the firm could not appear before Norms Committee. Hence, it was decided to reject the application of the firm.	

Case No.	67 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001507AM25
RA File Number	09AX04000202 AM25
Licence No and	0911007468/24/06/2024

Date

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Fesoterodine Fumarate Extended – release Tablets 4 mg (Consists of Fesoterodine Fumarate 16.31 Kgs)	1 Number	1	Fesoterodine Fumarate	4.08 mg
Fesoterodine Fumarate Extended - release Tablets 8 mg (Consists of Fesoterodine Fumarate 43.49 Kgs)	1 Number	2	Fesoterodine Fumarate	8.16 mg

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

Case No.	68 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	PANACEA BIOTEC PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00001565AM25
RA File Number	05AX04000957 AM25
Licence No and Date	0511026325/26/06/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	69 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003571AM25
RA File Number	03AX04003210 AM25
Licence No and Date	0311037768/09/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0311036028 dated 05/08/2024, 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.
Alclox-250 Capsule. Cloxacillin Sodium Capsules USP 250mg. ((Each Capsule Containing Cloxacillin Sodium BP Equivalent To 250 Mg of Cloxacillin).	1376235 Numbers	1	Cloxacillin Sodium BP Compacted	382.52 kg.
Alclox-500 Capsule . Cloxacillin Sodium Capsules USP 500 Mg. ((Each Capsule Containing Cloxacillinsodium BP Equivalent To 500 Mg of Cloxacillin).	11698313 Numbers	2	Cloxacillin Sodium BP Compacted	6503.09 kg.
Lampyklox Capsule. Cloxacillin Capsule (250+250 mg) ((Each Capsule Containg Cloxacillin Sodium Equivalent To 250 mg of Cloxacillin)	2000000 Numbers	3	Cloxacillin Sodium BP Compacted	555.9 kg.
Alclox -125 Syrup. Cloxacillin Socium For Oral Solution USP ((Each 5ml Contains Cloxacillin sodium BP Equivalent To 125 Mg of Cloxacillin).	21000 Numbers	4	Cloxacillin Sodium BP Compacted	58.48 kg.

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

Case No.	70 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	PI INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003572AM25
RA File Number	13AX04000225 AM25
Licence No and Date	1311003391/09/10/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	71 / NC/3/MEET/May/202526/3													
Case Status	Case Approved													
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025													
HQ File Number	HQRNORM APPLY 00003592AM25													
RA File Number	05AX04002138 AM25													
Licence No and Date	0511028223/10/10/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Dec/202425/12 dated 10/12/2024 against advance authorization No. 0511026265 dated 21/06/2024, 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:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>Brinzolamide Ophthalmic</td><td>1 Number</td><td>1</td><td>Brinzolamide</td><td>51.00 mg/Vial</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Brinzolamide Ophthalmic	1 Number	1	Brinzolamide	51.00 mg/Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Brinzolamide Ophthalmic	1 Number	1	Brinzolamide	51.00 mg/Vial										

Suspension, 1% w/v 5ml (Sterile Eye Drops)((Each ml contains Brinzolamide 10 mg (Equivalent to 1150.000 Gm of Bulk Drug))			(Micronized and Sterile)	
Brinzolamide Ophthalmic Suspension, 1% w/v 10ml (Sterile Eye Drops)((Each ml contains Brinzolamide 10 mg (Equivalent to 1500.000 Gm of Bulk Drug))	1 Number	2	Brinzolamide (Micronized and Sterile)	102.00 mg/Vial
Brinzolamide Ophthalmic Suspension, 1% w/v 15ml (Sterile Eye Drops)((Each ml contains Brinzolamide 10 mg (Equivalent to 2250.000 Gm of Bulk Drug)(Total 4900.000 Gm of Bulk Drug)	1 Number	3	Brinzolamide (Micronized and Sterile)	153.00 mg/Vial

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

Case No.	72 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003593AM25
RA File Number	34AX04000557 AM25
Licence No and Date	3411005529/10/10/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Hexyl Acetate	1 kg	1	n-Hexanol (Lorol C6/ Nacol 6)	0.782 kg
		2	Acetic Acid	0.463 kg

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

Case No.	73 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003605AM25
RA File Number	03AX04003421 AM25
Licence No and Date	0311037850/11/10/2024

Norms Committee Decision:

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

Sl. No	Export Product	Quantity
1	Medical Cream and Ointments(Glycerine Vaseline and Paraffin Cream 250gm [Total Wt. 750000 Kgs(Net Cont:Gly112500Kgs,Vase 60000 Kgs, Para Liq 15000 Kgs, Ste 50% 15750Kgs, Ste95% 6750 Kgs, Cyclo18750Kgs,Sili3750 Kgs,Mac37500Kgs,Trie3750 Kgs)])	1 Number

S. No	Import Product	Quantity allowed.
1	Relevant Bulk Drugs	Net content in the export product plus 2% wastage.

2	Relevant Excipients	Net content in the export product plus 2% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy & General Notes.

Note:

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

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

Case No.	74 / NC/3/MEET/May/202526/3			
Case Status	Case Approved			
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025			
HQ File Number	HQRNORM APPLY 00003610AM25			
RA File Number	03AX04002821 AM25			
Licence No and Date	0311037863/11/10/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No. 0311037160 dated 16/09/2024, 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.
Meropenem For Injection (Meropenem Buffered Sterile (Containing NLT 84% Sterile Meropenem)	1 kg.	1	Meropenem Non-Sterile (Meropenem Trihydrate Non-Sterile)	0.8968 kg.
		2	Packing Material:Aluminium Canister (5kg) /Aluminium Bottle Anodized 2m (20l000t.8020xy) (Oneset Contains One Canister/Aluminium Bottle Anodized+Inlid+Outlid+Bromo Butyl Gasket / Chloro Butyl Plug 802 / 2t.802 And Tear Off Alu Cap)	As per packing policy and General Notes.

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

Case No.	75 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003617AM25
RA File Number	05AX04002239 AM25
Licence No and Date	0511028273/14/10/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tobramycin and Dexamethasone Ophthalmic Suspension 5ml ((Each ml contains Tobramycin 3 mg. & Dexamethasone 1mg (Equivalent to 3000 gm Tobramycin Bulk Drug and 1000 gm Dexamethasone Bulk Drug))	200000 Numbers	1	Tobramycin	3150 gm.
		2	Dexamethasone (Micronised)	1050 gm.
Tobramycin and Dexamethasone Ophthalmic Suspension 3ml ((Each ml contains Tobramycin 3 mg. & Dexamethasone 1mg (Equivalent to 2700 gm Tobramycin Bulk Drug and 900 gm Dexamethasone Bulk Drug))	300000 Numbers	3	Tobramycin (Raw Material / Standard Grade)	2835 gm.
		4	Dexamethasone (Micronised)	945 gm.
Tobramycin and Dexamethasone Ophthalmic Suspension 10ml ((Each ml	180000 Numbers	5	Tobramycin	5670 gm.

contains Tobramycin 3mg. & Dexamethasone 1mg (Equivalent to 5400gm Tobramycin Bulk Drug and 1800gm Dexamethasone Bulk Drug) (Total Equivalent to 11100gm Tobramycin Bulk Drug and 3700gm Dexamethasone Bulk Drug))		6	Dexamethasone (Micronised)	1890 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	76 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003619AM25
RA File Number	08AX04001094 AM25
Licence No and Date	0811012932/14/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0811010468 dated 09/01/2024, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Isosorbide Mononitrate Extended Release Tablets USP 60 Mg (Each Film Coated Extended Release Tablets Contains: Diluted Isosorbide Mononitrate (50% Diluted with L Actose Monohydrate) USP equivalent to Isosorbide Mononitrate 60 mg	1 Number	1	Isosorbide Mononitrate 50 percent Assay. Diluted ISMN (50% diluted with lactose monohydrate)	122.40 mg.

Isosorbide Mononitrate Extended Release Tablets USP 120 Mg (Each Film Coated Extended Release Tablets Contains : Diluted Isosorbide Mononitrate (50% Diluted With Lactose Monohydrate) USP equivalent to Isosorbide Mononitrate 120 mg	1 Number		Isosorbide Mononitrate 50 percent Assay. Diluted ISMN (50% diluted with lactose monohydrate)	244.80 mg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	77 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003620AM25
RA File Number	08AX04001096 AM25
Licence No and Date	0811012933/14/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Dec/202425/12 dated 10/12/2024 against advance authorization No. 0811011769 dated 07/06/2024, 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.
Bisoprolol Fumarate Tablets 1.25 Mg (Each Film Coated Tablet Contains: Bisoprolol Fumarate USP 1.25 mg.)	1 Number Tablet	1	Bisoprolol Fumarate USP	1.275 mg/1.25 mg Tablet
Bisoprolol Fumarate Tablets 2.5 Mg (Each Film Coated	1 Number Tablet	2	Bisoprolol Fumarate USP	2.55 mg/2.5 mg Tablet

Tablet Contains: Bisoprolol fumarate USP 2.5 mg)				
Bisoprolol Fumarate Tablets 5 Mg (Each Film Coated Tablet Contains: Bisoprolol Fumarate USP 5 mg)	1 Number Tablet	3	Bisoprolol Fumarate USP	5.10 mg/5 mg Tablet
Bisoprolol Fumarate Tablets 10 Mg (Each Film Coated Tablet Contains: Bisoprolol Fumarate USP 10 Mg)	1 Number Tablet	4	Bisoprolol Fumarate USP	10.20 mg/10 mg Tablet

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

Case No.	78 / NC/3/MEET/May/202526/3													
Case Status	Case Approved													
Party Name	TORRENT PHARMACEUTICALS LTD													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025													
HQ File Number	HQRNORM APPLY 00003621AM25													
RA File Number	08AX04001095 AM25													
Licence No and Date	0811012934/14/10/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Dec/202425/12 dated 10/12/2024 against advance authorization No. 0811011806 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Propafenone Tablets 150 Mg (Propafenon 150 Heumann) (Each Filmcoated Tablet Contains: Propafenone Hydrochloride Ph.</td><td>1 Number</td><td>1</td><td>Propafenone Hydrochloride EP</td><td>153 mg/ Tablet</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Propafenone Tablets 150 Mg (Propafenon 150 Heumann) (Each Filmcoated Tablet Contains: Propafenone Hydrochloride Ph.	1 Number	1	Propafenone Hydrochloride EP	153 mg/ Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Propafenone Tablets 150 Mg (Propafenon 150 Heumann) (Each Filmcoated Tablet Contains: Propafenone Hydrochloride Ph.	1 Number	1	Propafenone Hydrochloride EP	153 mg/ Tablet										

Eur. 150 Mg				
Propafenone Tablets 300 Mg (Propafenon 300 Heumann) (Each Film Coated Tablet Contains: Propafenone Hydrochloride Ph. Eur. 300 Mg	1 Number	2	Propafenone Hydrochloride EP	306 mg/ Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	79 / NC/3/MEET/May/202526/3																
Case Status	Case Approved																
Party Name	SHILPA PHARMA LIFESCIENCES LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025																
HQ File Number	HQRNORM APPLY 00003629AM25																
RA File Number	07AX04001144 AM25																
Licence No and Date	0711012555/14/10/2024																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. 07/AM21 dated 24.12.2020 against advance authorization No. 0710109729 dated 27.04.2016, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="3">Gemcitabine HCL</td><td rowspan="3">1 kg</td><td>1</td><td>2 Deoxy 2 2 Difluoro D Erythro Pentafulranous 1 Ulose 3 5 Dibenzoate</td><td>4.78 kg</td></tr><tr><td>2</td><td>Tetra Hydro Furan</td><td>4.60 kg</td></tr><tr><td>3</td><td>Methylene Dichloride</td><td>6.20 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Gemcitabine HCL	1 kg	1	2 Deoxy 2 2 Difluoro D Erythro Pentafulranous 1 Ulose 3 5 Dibenzoate	4.78 kg	2	Tetra Hydro Furan	4.60 kg	3	Methylene Dichloride	6.20 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Gemcitabine HCL	1 kg	1	2 Deoxy 2 2 Difluoro D Erythro Pentafulranous 1 Ulose 3 5 Dibenzoate	4.78 kg													
		2	Tetra Hydro Furan	4.60 kg													
		3	Methylene Dichloride	6.20 kg													

		4	N Acetyl Cytosine	2.92 kg
		5	Trimethyl Silyl Trifluoromethane Sulfonate	4.23 kg
		6	Methanol	6.20 kg

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

Case No.	80 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003633AM25
RA File Number	03AX04003448 AM25
Licence No and Date	0311037925/15/10/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	81 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	RUBICON RESEARCH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003634AM25
RA File Number	03AX04003517 AM25
Licence No and Date	0311037926/15/10/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Glipizide Tab 2.5 mg(Glipizide Tab 2.5 mg (Net content of Glipizide is 2126.60 kg and of Anhydrous Lactose is 61246.08 kg and Croscarmellose Sodium USP-NF (Ac-Di-Sol) 3402.56 kg))	1 Number	1	Glipizide USP	2.50 mg
		2	Anh. Lactose NF	72.00 mg
		3	Croscarmellose Sodium USP-NF (Ac-Di-Sol)	4.00 mg
Glipizide Tab 5 mg(Glipizide Tab 5 mg (Net content of Glipizide is 2126.60 kg and of Anhydrous Lactose is 61246.08 kg and Croscarmellose Sodium USP-NF (Ac-Di-Sol) 3402.56 kg))	1 Number	4	Glipizide USP	5.00 mg
		5	Anh. Lactose NF	144.00 mg
		6	Croscarmellose Sodium USP-NF (Ac-Di-Sol)	8.00 mg
Glipizide Tab 10 mg(Glipizide Tab 10 mg (Net content of Glipizide is 2126.60 kg and of Anhydrous Lactose is 61246.08 kg and Croscarmellose Sodium USP-NF (Ac-Di-Sol) 3402.56 kg))	1 Number	7	Glipizide USP	10.00 mg
		8	Anh. Lactose NF	288.00 mg
		9	Croscarmellose Sodium USP-NF (Ac-Di-Sol)	16.00 mg

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

Case No.	82 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003646AM25
RA File Number	34AX04000564 AM25
Licence No and Date	3411005540/15/10/2024
Norms Committee Decision:	

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

Case No.	83 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003648AM25
RA File Number	05AX04002240 AM25
Licence No and Date	0511028306/15/10/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sodium Valproate	1 kg	1	Activated Carbon	0.010 kg
		2	Diethyl Malonate	1.30 kg
		3	Hyflosupercel	0.003 kg
		4	N-Propyl Bromide	2.01 kg
		5	Sodium Hydroxide flakes (Caustic Soda)	0.250 kg

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

Case No.	84 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003659AM25
RA File Number	03AX04003386 AM25
Licence No and Date	0311037953/15/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202425/18 dated 17/03/2025 against advance authorization No. 0311035876 dated 26/07/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Carbamazepine Extended-Release Tablets USP 100 mg.(Each tablet contains (i) Carbamazepine 100 mg. (ii) Cellulose Acetate(CA-320S)-Eastman 35.04 mg. (iii) Eastman (TM Cellulose Acetate (CA398-10NF/EP)-5.28mg. Net content (i) 754.48 Kg (ii)264.37 Kg (iii) 39.84 Kg.)	1 Number	1	Carbamazepine	102.00 mg.
		2	Cellulose Acetate (CA 320S) Eastman	29.20 mg.
		3	Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)	4.40 mg.
Carbamazepine Extended-Release Tablets USP 200 mg.(Each tablet contains (i) Carbamazepine 200 mg. (ii) Cellulose Acetate (CA-320S)-Eastman 35.04 mg. (iii) Eastman (TM Cellulose Acetate (CA398-10NF/EP)-5.28 mg. Netcontent (i) 757.02 kg (ii)132.63	1 Number	4	Carbamazepine	204.00 mg.
		5	Cellulose Acetate (CA 320S) Eastman	29.20 mg.
		6	Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)	4.40 mg.

Kg (iii) 19.99 Kg.)				
Carbamazepine Extended-Release Tablets USP 400 mg. (Each tablet contains (i) Carbamazepine 400 mg. (ii) Cellulose Acetate (CA-320S) - Eastman 26.28mg. (iii) Eastman (TM Cellulose Acetate (CA398-10NF/EP) - 3.96 mg. Net content (i) 310.84Kg. (ii) 20.42Kg (iii) 3.08 Kg.)	1 Number	7	Carbamazepine	408.00 mg.
		8	Cellulose Acetate (CA 320S) Eastman	21.90 mg.
		9	Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)	4.40 mg.

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

Case No.	85 / NC/3/MEET/May/202526/3													
Case Status	Case Approved													
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025													
HQ File Number	HQRNORM APPLY 00003660AM25													
RA File Number	03AX04003508 AM25													
Licence No and Date	0311037954/15/10/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Aug/202425/8 dated 28/08/2024 against advance authorization No. 0311033331 dated 24/04/2024, 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>Doxycycline 100 mg Capsules</td><td>1 Number</td><td>1</td><td>Doxycycline Hyclate Ph. EUR</td><td>115.40 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Doxycycline 100 mg Capsules	1 Number	1	Doxycycline Hyclate Ph. EUR	115.40 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Doxycycline 100 mg Capsules	1 Number	1	Doxycycline Hyclate Ph. EUR	115.40 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	86 / NC/3/MEET/May/202526/3										
Case Status	Case Approved										
Party Name	UNIMAX CHEMICALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025										
HQ File Number	HQRNORM APPLY 00003662AM25										
RA File Number	03AX04003405 AM25										
Licence No and Date	0311037957/15/10/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Aug/202425/8 dated 28/08/2024 against advance authorization No. 0311033255 dated 22/04/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Azithromycin Dihydrate</td><td>1 kg</td><td>1</td><td>Azithromycin Amine</td><td>0.9434 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Azithromycin Dihydrate	1 kg	1	Azithromycin Amine	0.9434 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Azithromycin Dihydrate	1 kg	1	Azithromycin Amine	0.9434 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	87 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	BVC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003672AM25
RA File Number	34AX04000597 AM25
Licence No and Date	3411005544/16/10/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending	

Personal Hearing before Norms Committee to explain its case along with sample of the products.

Case No.	88 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003680AM25
RA File Number	03AX04003229 AM25
Licence No and Date	0311037995/16/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No. 0311030712 dated 06/02/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sodium Cromoglicate Eye Drops 13.5 Ml ((Each 13.5 Ml Vial Contains Sodium Cromoglicate 0.270 gm Net Wt of Bulk 89.910 Kgs))	1 Vial	1	Sodium Cromoglicate	0.2754 gm/13.5 ml vial
Sodium Cromoglicate Eye Drops 10 Ml (Allercrom Eye Drops 10 Ml) ((Each 10 Ml Vial Contains Sodium Cromoglicate 0.200 gm Net Wt of Bulk 84.534 Kgs))	1 Vial	2	Sodium Cromoglicate	0.204 gm./10 ml. vial
Sodium Cromoglicate Eye Drops 5 Ml (Allercrom Eye Drops 5 Ml And Cromolyn Sodium Eye Drops 5 Ml) ((Each 5 Ml Vial Contains Sodium Cromoglicate 0.100 gm Net Wt of Bulk 7.800	1 Vial	3	Sodium Cromoglicate	0.102 gm./5 ml. vial

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

Case No.	89 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	SV PLASTOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003682AM25
RA File Number	31AX04000348 AM24
Licence No and Date	3111003982/16/10/2024
Norms Committee Decision: The committee considered the request of the 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. Chemical name of export product. 2. Complete chemistry with material balance Molar weight of export and import. 3. Percentage Yield and stichiometric balance.	

Case No.	90 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	LITMUS ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003683AM25
RA File Number	03AX04003302 AM25
Licence No and Date	0311037996/16/10/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TCD Emulsifier	20000 kg.	1	Hexahydro Phthalic Anhydride HHPA	12336 kg.
		2	TCD Alcohol DM	7868 kg.

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

Case No.	91 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	SV PLASTOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003691AM25
RA File Number	31AX04000043 AM22
Licence No and Date	3111003987/17/10/2024
Norms Committee Decision: The committee considered the request of the firm for fixation of ad-hoc norms, and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Complete chemistry with material balance molecular weight of export and import 2. Percentage Yield and stichometric balance.	

Case No.	92 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003714AM25
RA File Number	03AX04003488 AM25
Licence No and Date	0311038037/17/10/2024
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Diclofenac Gel 3% 25g DE ((Net Wt. of Sodium Hyaluronate is 7.93 Kgs.))	1 Number	1	Sodium Hyaluronate	1.61 gm
Diclofenac Gel 3% 50g DE ((Net Wt. of Sodium Hyaluronate is 3.49 Kgs.))	1 Number	2	Sodium Hyaluronate	1.62 gm
Diclofenac Gel 3% 90g DE ((Net Wt. of Sodium Hyaluronate is 6.35 Kgs.))	1 Number	3	Sodium Hyaluronate	1.62 gm
DICLOFENAC GEL 3% 50g UK ((Net Wt. of Sodium Hyaluronate is 11.90 Kgs.))	1 Number	4	Sodium Hyaluronate	0.309 gm
DICLOFENAC GEL 3% 100g UK ((Net Wt. of Sodium Hyaluronate is 6.35 Kgs.))	1 Number	5	Sodium Hyaluronate	3.60 gm
Diclofenac Gel 3% 60g ES ((Net Wt. of Sodium Hyaluronate is 61.89 Kgs.))	1 Number	6	Sodium Hyaluronate	8.41 gm
Diclofenac Gel 3% 90g ES ((Net Wt. of Sodium Hyaluronate is 2.86 Kgs.))	1 Number	7	Sodium Hyaluronate	0.481 gm

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

Case No.	93 / NC/3/MEET/May/202526/3
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Case Status	Case Approved													
Party Name	NEOGEN CHEMICALS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025													
HQ File Number	HQRNORM APPLY 00003723AM25													
RA File Number	03AX04003562 AM25													
Licence No and Date	0311038044/18/10/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0311034124 dated 27/05/2024, 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Ethyl Isobutyrate</td><td>1 kg.</td><td>1</td><td>Isobutyric Acid</td><td>0.948 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ethyl Isobutyrate	1 kg.	1	Isobutyric Acid	0.948 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Ethyl Isobutyrate	1 kg.	1	Isobutyric Acid	0.948 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	94 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003724AM25
RA File Number	03AX04003565 AM25
Licence No and Date	0311038045/18/10/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant information / documents from the firm:	

Case No.	95 / NC/3/MEET/May/202526/3			
Case Status	Case Approved			

Party Name	JUBILANT GENERICS LIMITED																				
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025																				
HQ File Number	HQRNORM APPLY 00003727AM25																				
RA File Number	05AX04002287 AM25																				
Licence No and Date	0511028382/18/10/2024																				
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <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>Cyclobenzaprine Hydrochloride Tablets 5 Mg</td><td>1 Number</td><td>1</td><td>Cyclobenzaprine Hydrochloride</td><td>5.10 mg</td></tr> <tr> <td>Cyclobenzaprine Hydrochloride Tablets 7.5 Mg</td><td>1 Number</td><td>2</td><td>Cyclobenzaprine Hydrochloride</td><td>7.65 mg</td></tr> <tr> <td>Cyclobenzaprine Hydrochloride Tablets 10 Mg</td><td>1 Number</td><td>3</td><td>Cyclobenzaprine Hydrochloride</td><td>10.20 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.	Cyclobenzaprine Hydrochloride Tablets 5 Mg	1 Number	1	Cyclobenzaprine Hydrochloride	5.10 mg	Cyclobenzaprine Hydrochloride Tablets 7.5 Mg	1 Number	2	Cyclobenzaprine Hydrochloride	7.65 mg	Cyclobenzaprine Hydrochloride Tablets 10 Mg	1 Number	3	Cyclobenzaprine Hydrochloride	10.20 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																	
Cyclobenzaprine Hydrochloride Tablets 5 Mg	1 Number	1	Cyclobenzaprine Hydrochloride	5.10 mg																	
Cyclobenzaprine Hydrochloride Tablets 7.5 Mg	1 Number	2	Cyclobenzaprine Hydrochloride	7.65 mg																	
Cyclobenzaprine Hydrochloride Tablets 10 Mg	1 Number	3	Cyclobenzaprine Hydrochloride	10.20 mg																	

Case No.	96 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003735AM25
RA File Number	05AX04002293 AM25
Licence No and Date	0511028402/18/10/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxepin Hydrochloride Capsules USP 10 mg.	1 Number	1	Doxepin HCL	11.353 mg
Doxepin Hydrochloride Capsules USP 25 mg.	1 Number	2	Doxepin HCL	28.384 mg
Doxepin Hydrochloride Capsules USP 50 mg.	1 Number	3	Doxepin HCL	56.766 mg
Doxepin Hydrochloride Capsules USP 75 mg.	1 Number	4	Doxepin HCL	85.152 mg
Doxepin Hydrochloride Capsules USP 100 mg.	1 Number	5	Doxepin HCL	113.538 mg

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

Case No.	97 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003737AM25
RA File Number	52AX04000217 AM25
Licence No and Date	5211010354/18/10/2024

Norms Committee Decision:

The committee considered the request of the 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. Please furnish complete chemistry with molecular weight and percentage yield on molar basis for manufacture of DARO-III from its basic stage.

Case No.	98 / NC/3/MEET/May/202526/3													
Case Status	Case Approved													
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025													
HQ File Number	HQRNORM APPLY 00003746AM25													
RA File Number	03AX04003569 AM25													
Licence No and Date	0311038096/21/10/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Aminowel 5% Infusion 250ml</td><td>310000 Numbers</td><td>1</td><td>Glycine EP</td><td>284.81 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Aminowel 5% Infusion 250ml	310000 Numbers	1	Glycine EP	284.81 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Aminowel 5% Infusion 250ml	310000 Numbers	1	Glycine EP	284.81 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	99 / NC/3/MEET/May/202526/3			
Case Status	Case Approved			
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025			
HQ File Number	HQRNORM APPLY 00003748AM25			
RA File Number	03AX04003491 AM25			
Licence No and Date	0311038102/21/10/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Rosuvastatin Tablet BP /USP10 mg.	1 Number	1	Tert-butyl2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl) acetate)	10.608 mg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	100 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003749AM25
RA File Number	03AX04003589 AM25
Licence No and Date	0311038089/21/10/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Fenoterol Hydrobromide and Ipratropium Bromide Solution for Inhalation (0.5mg+0.25mg/ml) (20 ml) ((Net Wt. of Fenoterol Hydrobromide is Qty. 500.00 Grams and Ipratropium Bromide is Qty. 250.00 Grams))	50000 Numbers	1	Fenoterol Hydrobromide	510 gm
		2	Ipratropium Bromide	255 gm
Fenoterol Hydrobromide and Ipratropium Bromide Solution for Inhalation (0.5mg+0.25mg/ml) (20 ml x 5) (Net Wt. of Fenoterol Hydrobromide is Qty. 2500.00 Grams and Ipratropium Bromide is	50000 Numbers	3	Fenoterol Hydrobromide	2550 gm
		4	Ipratropium Bromide	1275 gm

Qty. 1250.00 Grams))

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

Case No.	101 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003757AM25
RA File Number	03AX04003157 AM25
Licence No and Date	0311038087/21/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0311036037 dated 03/08/2024, 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.
Moxileb Kid Tablet (Amoxicillin Tablet 125mg) ((Each Tablet Containing Amoxicillin Trihydrate Equivalent To 125 Mg of Amoxicillin) Net Content of Import/Exempt Material Used In Export Product 1) Amoxicillin Trihydrate BP (Compacted) -71.755 kgs (Excl 2% Wastage))	1 Number	1	Amoxicillin Trihydrate BP Compacted	146.32 mg.
Moxileb-250dt.Amoxicillin Tablet 250 Mg ((Each Tablet Containing Amoxicillin Trihydrate Equivalent To 250mg of Amoxicillin). Net Content of Import/Exempt Material Used In Export Product 1)Amoxicillin Trihydrate BP (Compacted) -157.853 Kgs (Excl 2% Wastage))	1 Number	2	Amoxicillin Trihydrate BP Compacted	292.639 mg.

Moxileb-250 Capsule. (Amoxicillin Capsule 250 Mg) ((Each Capsule Containing Amoxicillin Trihydrate Equoalent To 250mg of Amoxicillin). Net Content of Import/Exempt Material Used In Export Product 1) Amoxicillin Trihydrate BP (Compacted) -1205.402 kgs (Excl 2% Wastage))	1 Number	3	Amoxicillin Trihydrate BP Compacted	292.639 mg.
Moxileb-500 Capsule. (Amoxicillin Capsule 500mg). ((Each Capsule Containing Amoxicillin Trihydrate Equivalent To 500 Mg of Amoxicillin). Net Content of Import/Exempt Materialused In Export Product 1) Amoxicillin Trihydrate BP (Compacted) -5737.13 kgs (Excl 2% Wastage))	1 Number	4	Amoxicillin Trihydrate BP Compacted	585.28 mg.
Moxileb Oral Suspension Amoxicillin Oral Suspension (Amoxicillin Syrup) 125mg/100 Ml Bottle. ((Each 5ml Contains Amoxicillin Trihydrate Euqivalent To 125 Mg of Amoxicillin). Net Content of Import/Exempt Material Used In Export Product 1) Amoxicillin Trihydrate BP - (Compacted) - 60.264 kgs (Excl 2% Wastage))	1 Number	5	Amoxicillin Trihydrate BP Compacted	2625.00 mg.
Moxileb Oral Suspension. Amoxicillin Oral Suspension (Amoxicillin Syrup) 250 Mg /100 Ml Bottle. ((Each 5ml Contains Amoxicillin Trihydrate Equivalent To 250 Mg of Amoxicillin). Net Content of Import/Exempt Material Used In Export Product 1) Amoxicillin Trihydrate BP (Compacted) - 120.54 Kgs (Excl 2% Wastage).)	1 Number	6	Amoxicillin Trihydrate BP Compacted	5250.00 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	102 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	MALIK LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003777AM25
RA File Number	05AX04002054 AM25
Licence No and Date	0511028020/22/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No. 0511024074 dated 26/02/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cefixime Tablets 200 mg (each tablet contains Cefixime USP (as Trihydrate) equivalent to Cefixime 200 mg on anhydrous basis), Pack size:1, Strip = 10 Tablets))	1 Number	1	Cefixime USP (As Trihydrate))	204.00 mg / Tablet

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

Case No.	103 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	BULI CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003786AM25
RA File Number	03AX04003625 AM25
Licence No and Date	0311038141/22/10/2024

Norms Committee Decision:

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

product/import item in meeting No. NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0311036306 dated 13/08/2024, 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 Item Name-1: N-BUTYL LITHIUM IN HEXANE (n-butyl Lithium) 15%

Qty:- 1 kg

Import Items:

Sl.No.	Item description	Qty. recoomendation
1	Lithium Metal	0.0406 kg
2	Butyl Chloride	0.270 kg
3	Hexane	1.760 kg

Export Item Name-2: N-BUTYL LITHIUM IN HEXANE (n-butyl Lithium) 23%

Qty:- 1 kg

Import Items:

Sl.No.	Item description	Qty. recoomendation
1	Lithium Metal	0.0650 kg
2	Butyl Chloride	0.432 kg
3	Hexane	1.574 kg

Export Item Name-3: N-BUTYL LITHIUM IN HEXANE (n-butyl Lithium) 30%

Qty:- 1 kg

Import Items:

Sl.No.	Item description	Qty. recoomendation
1	Lithium Metal	0.0812 kg

2	Butyl Chloride	0.540 kg
3	Hexane	1.450 kg

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

Case No.	104 / NC/3/MEET/May/202526/3										
Case Status	Case Approved										
Party Name	EAGLE CHEMICAL WORKS										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025										
HQ File Number	HQRNORM APPLY 00003795AM25										
RA File Number	03AX04003055 AM25										
Licence No and Date	0311038169/22/10/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Ferrous Fumarate BP/EP/FCC</td><td>1 kg</td><td>1</td><td>Fumaric Acid</td><td>0.727 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ferrous Fumarate BP/EP/FCC	1 kg	1	Fumaric Acid	0.727 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Ferrous Fumarate BP/EP/FCC	1 kg	1	Fumaric Acid	0.727 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	105 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	BHAGWATI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003824AM25
RA File Number	08AX04001178 AM25
Licence No and Date	0811012998/23/10/2024
Norms Committee Decision:	

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

1. A balanced chemical reaction indicating molecular weight of reactants and products with yield and justification.
2. The commercial value of the byproduct/s obtained during the process.
3. Calculation of the requirement of raw materials based on yield of the reaction.
4. A stoichiometric material balance on molar basis.

Case No.	106 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003840AM25
RA File Number	34AX04000615 AM25
Licence No and Date	3411005588/24/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No. 3411005383 dated 09/09/2024, 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.
Aldehyde C10 (Capric Aldehyde)	1 kg.	1	Fatty Alcohol C10 (98% purity)	1.40 kg.

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

Case No.	107 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	MEDICARE HYGIENE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025

HQ File Number	HQRNORM APPLY 00003843AM25
RA File Number	08AX04001190 AM25
Licence No and Date	0811013002/24/10/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	108 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	PRACHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003845AM25
RA File Number	08AX04001204 AM25
Licence No and Date	0811013007/24/10/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	109 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	ACUTAAS CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003846AM25
RA File Number	52AX04000212 AM25
Licence No and Date	5211010462/24/10/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	110 / NC/3/MEET/May/202526/3
Case Status	Case Deferred

Party Name	LAZERHEAD LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003851AM25
RA File Number	09AX04000499 AM25
Licence No and Date	0911008210/24/10/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	111 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003868AM25
RA File Number	08AX04001241 AM25
Licence No and Date	0811013030/25/10/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	112 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003874AM25
RA File Number	03AX04003742 AM25
Licence No and Date	0311038273/27/10/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Apr/202526/1 dated 25/04/2025 against advance authorization No. 0311037446 dated 26/09/2024, 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.
Artemether	1 kg	1	Artemisinin	1.04 kg.

Note: NC also decided to make new SION on the above norms.

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

Case No.	113 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003896AM25
RA File Number	34AX04000632 AM25
Licence No and Date	3411005604/28/10/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Adapalene and BPO Topical Gel 0.3% / 2.5% - 45 Gm Pump (Adapalene and BPO Topical Gel 0.3% / 2.5% - 45 gm Pump Adapalene and Benzoyl Peroxide Topical Gel 0.3% / 2.5% Net content of of Adapalene = 10.53 kgs and Benzoyl Peroxide Hydrous = 87.75 kgs.)	78000 Numbers	1	Benzoyl Peroxide Hydrous USP	89.505 kg

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

Case No.	114 / NC/3/MEET/May/202526/3										
Case Status	Case Approved										
Party Name	MANKIND PHARMA LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025										
HQ File Number	HQRNORM APPLY 00003908AM25										
RA File Number	05AX04002457 AM25										
Licence No and Date	0511028610/28/10/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Sep/202425/9 dated 10/10/2024 against advance authorization No. 0511016882 dated 17/01/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Formoterol Fumarate Inhalation Solution 20 mcg /2 mL (0.02 mg/2 ml), ((filling volume 2.1 ml in each number))</td><td>3594000 Numbers</td><td>1</td><td>Formoterol Fumarate Dihydrate USP</td><td>75.474 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Formoterol Fumarate Inhalation Solution 20 mcg /2 mL (0.02 mg/2 ml), ((filling volume 2.1 ml in each number))	3594000 Numbers	1	Formoterol Fumarate Dihydrate USP	75.474 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Formoterol Fumarate Inhalation Solution 20 mcg /2 mL (0.02 mg/2 ml), ((filling volume 2.1 ml in each number))	3594000 Numbers	1	Formoterol Fumarate Dihydrate USP	75.474 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	115 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	WEST BENGAL CHEMICAL INDUSTRIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003915AM25
RA File Number	02AX04000478 AM25
Licence No and Date	0211007515/28/10/2024
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ferric Maltol	1 kg	1	Maltol	0.962 kg

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

Case No.	116 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003926AM25
RA File Number	03AX04003723 AM25
Licence No and Date	0311038315/29/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0311036028 dated 05/08/2024, 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.
Alclox-250 Capsule. Cloxacillin Sodium Capsules USP 250 mg. ((Each Capsule Containing Cloxacillin Sodium BP Equivalent To 250 mg of Cloxacillin). Net content of Import/Exempt Material used In Export Products 1) Cloxacillin Sodium BP (Compacted) -291.405 kgs (Excluding 2% Wastage).)	1376235 Numbers	1	Cloxacillin Sodium BP Compacted	382.52 kg.
Alclox-500 Capsule . Cloxacillin Sodium Capsules Usp 500 mg. ((Each Capsule Containing Cloxacillin sodium BP equivalent	6389248 Numbers	2	Cloxacillin Sodium BP Compacted	3551.78 kg.

to 500 mg of cloxacillin).Net content of import/Exempt material used in Export Products 1) Cloxacillin Sodium Bp (Compacted) -1774.941 kgs (Excluding 2% Wastage).)				
Alclox -125 Syrup. Cloxacillin Socium for Oral Solution USP ((Each 5ml Contains Cloxacillin sodium BP equivalent to 125 mg of cloxacillin). Net content of import/Exempt material used in Export Product 1) Cloxacillin Sodium Bp (Compacted) -57.33 Kgs (Excluding 2% Wastage).)	21000 Numbers	3	Cloxacillin Sodium BP Compacted	58.48 kg.

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

Case No.	117 / NC/3/MEET/May/202526/3													
Case Status	Case Approved													
Party Name	TORRENT PHARMACEUTICALS LTD													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025													
HQ File Number	HQRNORM APPLY 00003937AM25													
RA File Number	08AX04001290 AM25													
Licence No and Date	0811013104/29/10/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No. 0311031277 dated 16/02/2024, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Indapamide SR 1.5 mg Tablets (Indapamid heumann 1.5 Mg Tablets) (Each Film Coated Sustained Release</td><td>1 Number</td><td>1</td><td>Indapamide EP</td><td>1.53 mg/Tablet</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Indapamide SR 1.5 mg Tablets (Indapamid heumann 1.5 Mg Tablets) (Each Film Coated Sustained Release	1 Number	1	Indapamide EP	1.53 mg/Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Indapamide SR 1.5 mg Tablets (Indapamid heumann 1.5 Mg Tablets) (Each Film Coated Sustained Release	1 Number	1	Indapamide EP	1.53 mg/Tablet										

Tablet Contains: Indapamide PH. EUR.1.5MG. Net Content of Active Ingredient Indapamide EP Should Not Be Less Than 84.00 Kgs.)				
Indapamide Tablets 2.5 Mg (Indapamid heumann 2.5 Mg Tablets) (Each Film Coated Tablet Contains : Indapamide PH. EUR. 2.5 Mg Equivalent to Indapamide In Net Content of Active Ingredient Indapamide EP Should Not Be Less Than 112.050 Kgs.)	1 Number	2	Indapamide EP	2.55 mg./Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	118 / NC/3/MEET/May/202526/3
Case Status	Case Deferred
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003943AM25
RA File Number	09AX04000560 AM25
Licence No and Date	0911008287/29/10/2024
Norms Committee Decision:	
The case is under consideration and TE was requested to expedite his comments.	

Case No.	119 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	KOPRAN LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003946AM25
RA File Number	03AX04003754 AM25
Licence No and Date	0311038370/30/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Dec/202425/12 dated 10/12/2024 against advance authorization No . 0711011477 dated 06/06/2024, 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.
Amoxicillin 250mg and Flucloxacillin 250 mg Capsules (Macropen 500 Mg Capsules (Each Capsule Contains Amoxicillin Trihydrate Equivalent to 250 mg of Amoxicillin and Flucloxacillin Sodium Equivalent to 250mg of Anhydrous Flucloxacillin))	1 Number Capsule	1	Amoxicillin Trihydrate	292.68 mg / Capsule
		2	Flucloxacillin Sodium	277.47 mg / Capsule
Amoxicillin 125 Mg and Flucloxacillin 125 Mg Oral Solution, 100 Ml Bottle (Macropens 100 Ml Syrup) (Amoxicillin 125mg/5ml & Flucloxacillin 125mg/5ml Oral Solution,100ml Bottle (Macropen S 100 ml syrup) (Each 5ml Contains Amoxicillin Trihydrate Equivalent to 125 mg of Amoxicillin and Flucloxacillin Sodium Equivalent to 125 mg of Anhydrous Flucloxacillin))	1 Number Bottle	3	Amoxicillin Trihydrate	3012.83 mg/Bottle
		4	Flucloxacillin Sodium	2856.33 mg / Bottle

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

Case No.	120 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003948AM25
RA File Number	08AX04001293 AM25
Licence No and Date	0811013115/30/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Aug/202425/8 dated 28/08/2024 against advance

authorization No. 0811011225 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Metamizole Sodium, Pitofenone Hydrochloride & Fenpiverinium Bromide Tablets. (Spasmalin Tablets 500mg). (Each coated tablet contains 500 MG of Metamizole Sodium B P mg Excipients...as per q.s. Net content of Metamizole Sodium B P should not be less than 20000.00 kg in export item.)	1 Number	1	Metamizole Sodium B. P.	510 mg/Tablet

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

Case No.	121 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003949AM25
RA File Number	08AX04001303 AM25
Licence No and Date	0811013116/30/10/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Feb/202425/17 dated 25/02/2025 against advance authorization No. 0811009637 dated 11/10/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Co-Careldopa Tablets 250 MG + 25 MG (TIDOMET /	1 Number	1	LEVODOPA BP	255.0 mg./Tablet

TIDOMET FORTE, Levodopa 250 Mg + Carbidopa 25 mg Tablets) (Each uncoated tablet contains Levodopa BP 250 Mg				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	122 / NC/3/MEET/May/202526/3										
Case Status	Case Approved										
Party Name	SENTISS PHARMA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025										
HQ File Number	HQRNORM APPLY 00003950AM25										
RA File Number	05AX04002498 AM25										
Licence No and Date	0511028660/30/10/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Aug/202425/8 dated 28/08/2024 against advance authorization No. 0511015566 dated 01/11/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Mydrimax Eye Drops 5ml Vials (Each ml contains Tropicamide 0.8%)</td><td>1 Number</td><td>1</td><td>Tropicamide</td><td>40.8 mg / 5ml Vial</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Mydrimax Eye Drops 5ml Vials (Each ml contains Tropicamide 0.8%)	1 Number	1	Tropicamide	40.8 mg / 5ml Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Mydrimax Eye Drops 5ml Vials (Each ml contains Tropicamide 0.8%)	1 Number	1	Tropicamide	40.8 mg / 5ml Vial							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	123 / NC/3/MEET/May/202526/3
Case Status	Case Approved

Party Name	NEOGEN CHEMICALS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025													
HQ File Number	HQRNORM APPLY 00003959AM25													
RA File Number	03AX04003719 AM25													
Licence No and Date	0311038388/30/10/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No. NC/3/MEET/Mar/202425/19 dated 27/03/2025 against advance authorization No. 0311034124 dated 27/05/2024, 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:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>ETHYL ISOBUTYRATE</td><td>1 kg.</td><td>1</td><td>ISOBUTYRIC ACID</td><td>0.948 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ETHYL ISOBUTYRATE	1 kg.	1	ISOBUTYRIC ACID	0.948 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
ETHYL ISOBUTYRATE	1 kg.	1	ISOBUTYRIC ACID	0.948 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	124 / NC/3/MEET/May/202526/3										
Case Status	Case Approved										
Party Name	KLJ PLASTICIZERS LIMITED.										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025										
HQ File Number	HQRNORM APPLY 00003962AM25										
RA File Number	05AX04001685 AM25										
Licence No and Date	0511028475/30/10/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting No.NC/3/MEET/Jun/202324/6 dated 14.06.2023 against advance authorization No. 0511017678 dated 09.03.2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>TRI ETHYL CITRATE</td><td>1 kg</td><td>1</td><td>CITRIC ACID</td><td>0.726 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	TRI ETHYL CITRATE	1 kg	1	CITRIC ACID	0.726 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
TRI ETHYL CITRATE	1 kg	1	CITRIC ACID	0.726 kg							

(TEC)		2	DENATURED ETHYL ALCOHOL	0.526 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	125 / NC/3/MEET/May/202526/3
Case Status	Case Approved
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202526/ 3 and 04/06/2025
HQ File Number	HQRNORM APPLY 00003964AM25
RA File Number	03AX04003631 AM25
Licence No and Date	0311038397/30/10/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CYCLOPENTYL BROMIDE	1 kg.	1	CYCLOPENTENE	0.609 kg.
		2	HYDROBROMIC ACID 48%	1.189 kg.

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