



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III**MEETING No.** NC/3/MEET/Mar/202324/26**DATED:** 22/03/2024Please Note

- I. For information of exporters, Norms Committee - III handles all cases pertaining to fixation/ratification of norms for Export Products falling under ITC (HS) Chapter 29, 30 .Communications in respect of cases/pertaining to NC- III may be sent to email address: nc3.dgft@nic.in
- II. The Norms Committee has taken decision only with respect to technical aspect/wastage norms. While redeeming the applications, RAs should check that the applicant has fulfilled all requirements as prescribed in policy/procedure including those in Policy Circulars issued from time to time or any other provisions under FTP/HBP for EODC.
- III. Wherever the Committee has fixed Norms, the concerned RA may ensure that AA is issued on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less.
- IV. RAs shall also ensure compliance of SION General Notes and Chapter Notes wherever applicable.
- V. RAs shall ensure that authorization is issued or redeemed based on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less. In this regard full compliance of the provisions of Para 4.12 of FTP, Para 4.16; Para 4.21; and Para 4.51 of HBP shall be made.

Meeting No. NC/3/MEET/Mar/202324/26 dated 22/03/2024 of Norms Committee - III for the year 2023-24 was held on 22/03/2024 under the Chairmanship of Rakesh Kumar, Additional DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2023.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
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1	Rakesh Kumar, Addl. DGFT	DGFT(HQ)
2	Raman Kumar, Deputy DGFT	DGFT(HQ)
3	NAND Lal, Technical Consultant	DPIIT
4	SHAISH KUMAR, Technical Consultant	DGFT
5	DINESHNARAIN MATHUR, Technical Consultant	DGFT
6	Nand Lal, Technical Consultant	DGFT
7	Uttam Dey Sarkar, ASO	Directorate General of Foreign Trade, Delhi

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008231AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	2 / NC/3/MEET/Mar/202324/26																			
Case Status	Case Approved																			
Party Name	ZYDUS LIFESCIENCES LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024																			
HQ File Number	HQRNORM APPLY 00008565AM24																			
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 product in meeting No.NC/3/MEET/Jan/202324/20 dated 18/01/2024 against advance authorization No.0811007464 dated 07/03/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																				
<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="4">MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 7 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))</td><td rowspan="4">1 Number</td><td>1</td><td>MEMANTINE HYDROCHLORIDE USP</td><td>7.14 mg.</td></tr><tr><td>2</td><td>SUGAR SPHERES (NON-PAREIL) NF</td><td>30.60 mg.</td></tr><tr><td>3</td><td>HYPROMELLOSE 5 CPS 2910 USP</td><td>3.824 mg.</td></tr><tr><td>4</td><td>HYPROMELLOSE 3 CPS 2910 USP</td><td>3.06 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 7 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))	1 Number	1	MEMANTINE HYDROCHLORIDE USP	7.14 mg.	2	SUGAR SPHERES (NON-PAREIL) NF	30.60 mg.	3	HYPROMELLOSE 5 CPS 2910 USP	3.824 mg.	4	HYPROMELLOSE 3 CPS 2910 USP	3.06 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 7 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))	1 Number	1	MEMANTINE HYDROCHLORIDE USP	7.14 mg.																
		2	SUGAR SPHERES (NON-PAREIL) NF	30.60 mg.																
		3	HYPROMELLOSE 5 CPS 2910 USP	3.824 mg.																
		4	HYPROMELLOSE 3 CPS 2910 USP	3.06 mg.																

		5	TRIETHYL CITRATE NF	0.829 mg.
		6	TALC PH EUR/USP	1.594 mg.
MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 14 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))	1 Number	7	MEMANTINE HYDROCHLORIDE USP	14.28 mg.
		8	SUGAR SPHERES (NON-PAREIL) NF	61.20 mg.
		9	HYPROMELLOSE 5 CPS 2910 USP	7.648 mg.
		10	HYPROMELLOSE 3 CPS 2910 USP	6.12 mg.
		11	TRIETHYL CITRATE NF	1.658 mg.
		12	TALC PH EUR/USP	3.188 mg.
MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 21 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))	1 Number	13	MEMANTINE HYDROCHLORIDE USP	21.42 mg.
		14	SUGAR SPHERES (NON-PAREIL) NF	91.80 mg.
		15	HYPROMELLOSE 5 CPS 2910 USP	11.472 mg.
		16	HYPROMELLOSE 3 CPS 2910 USP	9.18 mg.
		17	TRIETHYL CITRATE NF	2.487 mg.
		18	TALC PH EUR/USP	4.782 mg.
MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 28 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))	1 Number	19	MEMANTINE HYDROCHLORIDE USP	28.56 mg.
		20	SUGAR SPHERES (NON-PAREIL) NF	122.40 mg.
		21	HYPROMELLOSE 5 CPS 2910 USP	15.296 mg.

		22	HYPROMELLOSE 3 CPS 2910 USP	12.24 mg.
		23	TRIETHYL CITRATE NF	3.316 mg.
		24	TALC PH EUR/USP	6.376 mg.
MEMANTINE HYDROCHLORIDE TABLETS 5 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))	1 Number	25	MEMANTINE HYDROCHLORIDE USP	5.10 mg.
		26	TALC PH EUR/USP	1.02 mg.
		27	CROSCARMELLOSE SODIUM NF	5.61 mg.
		28	DIBASIC CALCIUM PHOSPHATE DIHYDRATE USP	73.95 mg.
		29	MAGNESIUM STEARATE PH.E/NF/JP	1.02 mg.
MEMANTINE HYDROCHLORIDE TABLETS 10 MG ((ACTIVE PHARMACEUTICAL INGREDIENT: MEMANTINE HYDROCHLORIDE USP))	1 Number	30	MEMANTINE HYDROCHLORIDE USP	10.20 mg.
		31	TALC PH EUR/USP	2.04 mg.
		32	CROSCARMELLOSE SODIUM NF	11.22 mg.
		33	DIBASIC CALCIUM PHOSPHATE DIHYDRATE USP	147.90 mg.
		34	MAGNESIUM STEARATE PH.E/NF/JP	2.04 mg.

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

Case No.	3 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred

Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008586AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	4 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	GULSHAN POLYOLS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008806AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Complete calculation for the requirement of Export item from yellow maize. 2. To fill Annexure to Appendix-4E for the both imported and indigenous items. 3. The value of by-product obtained during the process with evidence. 4. Certificate of Analysis (CoA) report of Yellow Maize indicating moisture content in it. 5. Production/Consumption data enclosed with the application, indicates consumption of 1.4 MT/MT of production of Sorbitol 70% whereas in application ratio has been indicated as 1.00 MT/MT. 6. Norms fixed in the past, if any, by the Norms Committee.	

Case No.	5 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM REVIW00000095AM24
RA File Number	522404000013 AM21
Licence No and	5210043424/08/06/2020

Date	
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. To give proper chemistry as per the inputs requested for. 2. Complete justification for higher norms asked for, making the revised quantity. 3. Stoichiometric Material balance on a molar basis. 4. Production/Consumption date for the last three years durly certified by CA 5. End use of export product.	

Case No.	6 / NC/3/MEET/Mar/202324/26																
Case Status	Case Approved																
Party Name	VINYL PRODUCTS PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024																
HQ File Number	HQRNORM REVIW00008920AM24																
RA File Number	05AX04002728 AM23																
Licence No and Date	0511016407/15/12/2022																
Norms Committee Decision:																	
Decision : The Committee considered the request of applicant for correction of export description and on the basis of request, the Committee deliberately felt that there was a typographical error in the export description, therefore, it was decided to correct the description of export product as per license:																	
<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">PHTHALATE (PVC) PLASTICIZER (DOTP)</td><td rowspan="2">1 kg.</td><td>1</td><td>PURE TERA PHTHALIC ACID</td><td>0.447 kg.</td></tr><tr><td>2</td><td>2 ETHYL HEXANOL</td><td>0.680 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PHTHALATE (PVC) PLASTICIZER (DOTP)	1 kg.	1	PURE TERA PHTHALIC ACID	0.447 kg.	2	2 ETHYL HEXANOL	0.680 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
PHTHALATE (PVC) PLASTICIZER (DOTP)	1 kg.	1	PURE TERA PHTHALIC ACID	0.447 kg.													
		2	2 ETHYL HEXANOL	0.680 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	7 / NC/3/MEET/Mar/202324/26										
Case Status	Case Approved										
Party Name	LACTOSE (INDIA) LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024										
HQ File Number	HQRNORM REVIW00008977AM24										
RA File Number	03AX04005338 AM23										
Licence No and Date	0311021031/30/01/2023										
Norms Committee Decision:											
Decision : The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>LACTULOSE CONCENTRATE USP/EP/LACTULOSE SOLUTION USP/EP/LACTULOSE FOOD GRADE (Assy not less than 95%)</td><td>1 kg.</td><td>1</td><td>Food Grade Lactose/ Edible Grade Lactose/ Refined Edible Grade Lactose / Lactose Monohydrate BP/EP/USP-NF / Lactose 100 Mesh</td><td>1.00 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	LACTULOSE CONCENTRATE USP/EP/LACTULOSE SOLUTION USP/EP/LACTULOSE FOOD GRADE (Assy not less than 95%)	1 kg.	1	Food Grade Lactose/ Edible Grade Lactose/ Refined Edible Grade Lactose / Lactose Monohydrate BP/EP/USP-NF / Lactose 100 Mesh	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
LACTULOSE CONCENTRATE USP/EP/LACTULOSE SOLUTION USP/EP/LACTULOSE FOOD GRADE (Assy not less than 95%)	1 kg.	1	Food Grade Lactose/ Edible Grade Lactose/ Refined Edible Grade Lactose / Lactose Monohydrate BP/EP/USP-NF / Lactose 100 Mesh	1.00 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	8 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM REVIW00008930AM24
RA File Number	03AX04003005 AM24
Licence No and Date	0311027533/03/10/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	9 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	UNIMAX LABORATORIES
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007665AM24
RA File Number	05AX04002801 AM24
Licence No and Date	0511022533/01/01/2024

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.
Amoxicillin Capsules BP, 500 mg(Each Capsules contains Amoxicillin BP (As Trihydrate))	1 Number	1	Amoxicillin Trihydrate BP	585.28 mg/Capsule
Amoxicillin Tablets USP, 1000 mg(Each Tablet contains Amoxicillin USP (As Trihydrate))	1 Number	2	Amoxicillin Trihydrate USP	1170.55 mg/Tablet

Note: The RA to examine export item description in Shipping Bill whether the term “ Trihydrate” appears or not. The above wastage shall be allowed with the condition that “Trihydrate) is mentioned in Export Product.

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

Case No.	10 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	ZEOLITES AND ALLIED PRODUCTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007666AM24
RA File Number	03AX04004399 AM24
Licence No and Date	0311029806/01/01/2024
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/23 dated 19/02/2024** against advance authorization **No.0311028138 dated 25/10/2023** , 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.
Cyclopentanone(CAS No. 120- 92-3)	1 kg.	1	Adipic Acid	1.93 kg.

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

Case No.	11 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007667AM24
RA File Number	03AX04004448 AM24
Licence No and Date	0311029807/01/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	12 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007671AM24
RA File Number	03AX04004482 AM24
Licence No and Date	0311029813/01/01/2024
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.
Fluorouracil INJ BP 1000 MG/20 ML	1 Vial	1	Fluorouracil IP/BP	1050 mg/Vial

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

Case No.	13 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	TRANSPEK INDUSTRY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007693AM24
RA File Number	34AX04000716 AM24
Licence No and Date	3411004490/02/01/2024

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.
ISONONANOYL CHLORIDE	1 kg.	1	ISONONANOIC ACID	0.942 kg.

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

Case No.	14 / NC/3/MEET/Mar/202324/26
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Case Status	Case Approved										
Party Name	HARMAN FINOCHEM LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024										
HQ File Number	HQRNORM APPLY 00007697AM24										
RA File Number	03AX04004502 AM24										
Licence No and Date	0311029840/03/01/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/24 dated 05/03/2024 against advance authorization No.0311014263 dated 29/04/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Sacubitril+Calcium (Sacubitril Calcium)</td><td>1 kg.</td><td>1</td><td>2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)</td><td>1.237 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	15 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007698AM24
RA File Number	03AX04004501 AM24
Licence No and Date	0311029842/03/01/2024
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/24 dated 05/03/2024 against advance authorization No.0311014263 dated 29/04/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

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

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

Case No.	16 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	AARTI INDUSTRIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007699AM24
RA File Number	03AX04004508 AM24
Licence No and Date	0311029843/03/01/2024
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Stoichiometric material balance on a molar basis. 2. Calculation for the requirement of input chemicals indicating justification of wastage. 3. End use of export item.	

Case No.	17 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007702AM24
RA File Number	03AX04003989 AM24
Licence No and Date	0311029847/03/01/2024
Norms Committee Decision:	

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

- i. **End use of the export product.**
- ii. **Step wise manufacturing process.**
- iii. **Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.**
- iv. **Complete technical details as per Annexure to Appendix 4E for chemical products.**
- v. **Stoichiometric balance between import and export on molar basis.**
- vi. **Details of indigenous input with quantity.**

Case No.	18 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	BILCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007714AM24
RA File Number	31AX04000266 AM24
Licence No and Date	3111002947/03/01/2024
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Annexure to Appendix-4E with chemical reaction and flow chart.	

Case No.	19 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007715AM24
RA File Number	03AX04004142 AM24
Licence No and Date	0311029863/03/01/2024
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jun/202324/6 dated 14/06/2023 against advance authorization	

No.0311021534 dated 17/02/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Testosterone Topical Solution 30mg / 1.5 ml Pack Size 110ml (Each Actuation delivers : Testosterone USP 30mg Also contains Alcohol USP Approx. 49.55% w/v (QS to 100% w/v))	59000 Numbers	1	Testosterone USP	112.1 kg.
		2	Alcohol (Ethanol 95% v/v)	3215.5 kg.

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

Case No.	20 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007722AM24
RA File Number	05AX04003154 AM24
Licence No and Date	0511023042/03/01/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Dec/202223/15 dated 29/12/2022** against advance authorization **No.0511014015 dated 28/07/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cyclomed Eye Drops 1% 5ml (Each ml contains 10 mg of Cyclopentolate Hydrochloride)	1 Pack	1	Cyclopentolate HCL	51.00 mg.

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

Case No.	21 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007728AM24
RA File Number	09AX04000875 AM24
Licence No and Date	0911006481/03/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	22 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007770AM24
RA File Number	09AX04000867 AM24
Licence No and Date	0911006493/05/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	23 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007772AM24

RA File Number	09AX04000883 AM24
Licence No and Date	0911006495/05/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	24 / NC/3/MEET/Mar/202324/26																
Case Status	Case Approved																
Party Name	ALCHEMIE FINECHEM PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024																
HQ File Number	HQRNORM APPLY 00007782AM24																
RA File Number	03AX04004420 AM24																
Licence No and Date	0311029946/06/01/2024																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/May/202324/4 dated 26/05/2023 against advance authorization No.0311020895 dated 23/01/2023 , 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 rowspan="2">N,ETHYL ORTHOTOLUIDINE</td><td rowspan="2">1kg.</td><td>1</td><td>ORTHOTOLUIDINE</td><td>0.834 kg.</td></tr><tr><td>2</td><td>DENATURED ETHYL ALCOHOL</td><td>0.358 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	N,ETHYL ORTHOTOLUIDINE	1kg.	1	ORTHOTOLUIDINE	0.834 kg.	2	DENATURED ETHYL ALCOHOL	0.358 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
N,ETHYL ORTHOTOLUIDINE	1kg.	1	ORTHOTOLUIDINE	0.834 kg.													
		2	DENATURED ETHYL ALCOHOL	0.358 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	25 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024

and Date	
HQ File Number	HQRNORM APPLY 00007828AM24
RA File Number	08AX04001867 AM24
Licence No and Date	0811010468/09/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	26 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007829AM24
RA File Number	08AX04001863 AM24
Licence No and Date	0811010469/09/01/2024

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.
Opipramol Dihydrochloride Tablets 50 MG (OPIPRAMOL HEUMANN 50 MG) Each film coated tablet contains: Opipramol Dihydrochloride 50 mg Excipients....q.s. Net content of active ingredient Opipramol Dihydrochloride should not be less than 80.00 kgs in export product.	1 Number	1	Opipramol Dihydrochloride	51 mg/Tablet
Opipramol Dihydrochloride Tablets 100 MG (OPIPRAMOL HEUMANN 100 MG) Each film coated tablet contains: Opipramol Dihydrochloride 100 mg Excipients....q.s. Net content of	1 Number	2	Opipramol Dihydrochloride	102 mg/Tablet

active ingredient Opipramol Dihydrochloride should not be less than 109.000 kgs in export product.

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

Case No.	27 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007830AM24
RA File Number	08AX04001864 AM24
Licence No and Date	0811010470/09/01/2024

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.
CINNARIZINE AND DIMENHYDRINATE 20MG+40MG TABLETS (CINZATOR) (EACH UNCOATED TABLETS CONTAINS: CINNARIZINE PH. EUR. 20 MG & DIMENHYDRINATE PH. EUR. 40 MG NET CONTENT OF DIMENHYDRINATE SHOULD NOT BE LESS THAN 88.840 KGS IN EXPORT PRODUCT)	1 Number	1	DIMENHYDRINATE MICRONIZED PH.EUR	40.80 mg/Tablet

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

Case No.	28 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007856AM24
RA File Number	07AX04001598 AM24
Licence No and Date	0711010168/10/01/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/23 dated 19/02/2024** against advance authorization **No.0711009545 dated 26/10/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PREMIX OF NIFUROXAZIDE (PREMIX OF NIFUROXAZIDE (1 GM OF PREMIX CONTAINS 0.552 GMS OF NIFUROXAZIDE) Net content 3974.40 KG))	7200 kg.	1	NIFUROXAZIDE BP/EP	4014.146 kg.

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

Case No.	29 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007861AM24
RA File Number	03AX04004600 AM24
Licence No and	0311030078/10/01/2024

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:-														
<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>Delofine XL 10 mg Prolonged Release Tablets 28 s (Felodipine 10 mg Prolonged Release Tablets 28 s) ((1,07,140 Packs X 28 Tablets per Packs = 29,99,920 Tablets) (Total Weight of Export Product = 30.00 Kgs) (Net Content weight of Import Product = 31.85 kgs))</td> <td>1 Tablet</td> <td>1</td> <td>Felodipine Ph. Eur.</td> <td>10.2 mg/Tablet</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Delofine XL 10 mg Prolonged Release Tablets 28 s (Felodipine 10 mg Prolonged Release Tablets 28 s) ((1,07,140 Packs X 28 Tablets per Packs = 29,99,920 Tablets) (Total Weight of Export Product = 30.00 Kgs) (Net Content weight of Import Product = 31.85 kgs))	1 Tablet	1	Felodipine Ph. Eur.	10.2 mg/Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Delofine XL 10 mg Prolonged Release Tablets 28 s (Felodipine 10 mg Prolonged Release Tablets 28 s) ((1,07,140 Packs X 28 Tablets per Packs = 29,99,920 Tablets) (Total Weight of Export Product = 30.00 Kgs) (Net Content weight of Import Product = 31.85 kgs))	1 Tablet	1	Felodipine Ph. Eur.	10.2 mg/Tablet										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	30 / NC/3/MEET/Mar/202324/26								
Case Status	Case Approved								
Party Name	R.L.FINE CHEM PRIVATE LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024								
HQ File Number	HQRNORM APPLY 00007863AM24								
RA File Number	07AX04001615 AM24								
Licence No and Date	0711010174/10/01/2024								
Norms Committee Decision:									
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202324/25 dated 11/03/2024 against advance authorization No. 0711009827 dated 01/12/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-									
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					

NORTRIPTYLINE HCL(IP/BP/USP)	1 kg.	1	1 BROMO 3 CHLORO PROPANE	0.96 kg.
		2	TETRA HYDRO FURAN	0.71 kg.
		3	ACETONE	1.00 kg.
		4	TOLUENE	1.00 kg.

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

Case No.	31 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007864AM24
RA File Number	07AX04001614 AM24
Licence No and Date	0711010175/10/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	32 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007865AM24
RA File Number	07AX04001617 AM24
Licence No and Date	0711010176/10/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	33 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007866AM24
RA File Number	07AX04001599 AM24
Licence No and Date	0711010178/10/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	34 / NC/3/MEET/Mar/202324/26																
Case Status	Case Approved																
Party Name	R.L.FINE CHEM PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024																
HQ File Number	HQRNORM APPLY 00007874AM24																
RA File Number	07AX04001631 AM24																
Licence No and Date	0711010184/10/01/2024																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.10/82-ALC4/2018 dated 16/10/2018 against advance authorization No.0710112769 dated 02/02/2018 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<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">CHLORPROMAZINE HYDROCHLORIDE (BP/EP/USP/IP)</td><td rowspan="3">1 Kg.</td><td>1</td><td>2 CHLORO PHENOTHIAZINE</td><td>0.90 kg.</td></tr><tr><td>2</td><td>1 BROMO 3 CHLORO PROPANE</td><td>0.95 kg.</td></tr><tr><td>3</td><td>TOLUENE</td><td>Not allowed</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CHLORPROMAZINE HYDROCHLORIDE (BP/EP/USP/IP)	1 Kg.	1	2 CHLORO PHENOTHIAZINE	0.90 kg.	2	1 BROMO 3 CHLORO PROPANE	0.95 kg.	3	TOLUENE	Not allowed
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
CHLORPROMAZINE HYDROCHLORIDE (BP/EP/USP/IP)	1 Kg.	1	2 CHLORO PHENOTHIAZINE	0.90 kg.													
		2	1 BROMO 3 CHLORO PROPANE	0.95 kg.													
		3	TOLUENE	Not allowed													

		4	ACETONE	3.30 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	35 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007890AM24
RA File Number	03AX04004630 AM24
Licence No and Date	0311030104/11/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	36 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	UNIMAX LABORATORIES
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007901AM24
RA File Number	05AX04003229 AM24
Licence No and Date	0511023203/11/01/2024
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:-	
Certificate of Analysis (CoA) of import item from foreign supplier showing the actual potency.	

Case No.	37 / NC/3/MEET/Mar/202324/26										
Case Status	Case Approved										
Party Name	SENTISS PHARMA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024										
HQ File Number	HQRNORM APPLY 00007911AM24										
RA File Number	05AX04003160 AM24										
Licence No and Date	0511023216/11/01/2024										
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Sep/202324/14 dated 27/09/2023 against advance authorization No.0511020040 dated 25/07/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="197 950 1428 1276"> <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>INOKAIN EYE DROPS 0.4 PERCENT 5 ML (Each ml contains 4mg of Benoxinate Hydrochloride)(INOKAIN EYE DROPS 0.4 PERCENT 5 ML (Each ml contains 4mg of Benoxinate Hydrochloride))</td><td>1 Vial</td><td>1</td><td>Benoxinate HCL</td><td>20.4 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.	INOKAIN EYE DROPS 0.4 PERCENT 5 ML (Each ml contains 4mg of Benoxinate Hydrochloride)(INOKAIN EYE DROPS 0.4 PERCENT 5 ML (Each ml contains 4mg of Benoxinate Hydrochloride))	1 Vial	1	Benoxinate HCL	20.4 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
INOKAIN EYE DROPS 0.4 PERCENT 5 ML (Each ml contains 4mg of Benoxinate Hydrochloride)(INOKAIN EYE DROPS 0.4 PERCENT 5 ML (Each ml contains 4mg of Benoxinate Hydrochloride))	1 Vial	1	Benoxinate HCL	20.4 mg.							

Case No.	38 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	ABHILASH LIFE SCIENCES LLP
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007918AM24
RA File Number	32AX04000594 AM24
Licence No and Date	3211006159/11/01/2024
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.
PARACETAMOL DIRECTLY COMPRESSIBLE GRANULES 90% W/W (ACTIVE PHARMA INGREDIENT)	1 kg.	1	PARACETAMOL	0.909 kg.

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

Case No.	39 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007926AM24
RA File Number	52AX04000307 AM24
Licence No and Date	5211007035/12/01/2024
Norms Committee Decision:	
Decision: The case is under consideration for want of comments of TE.	

Case No.	40 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	CREDO LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007939AM24
RA File Number	09AX04000902 AM24
Licence No and Date	0911006573/12/01/2024
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Sep/202324/14 dated 27/09/2023** against advance authorization **No.0911005430 dated 18/07/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Azithromycin Taste Mask Pellets 7.5% (Each 1 Gram Taste Mask Pellets contains Azithromycin as Azithromycin Dihydrate - 75 mg)	21500 kg.	1	Azithromycin Dihydrate	1628.615 kg.

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

Case No.	41 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007961AM24
RA File Number	03AX04004656 AM24
Licence No and Date	0311030162/15/01/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/24 dated 05/03/2024** against advance authorization **No.0311014263 dated 29/04/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

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

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

Case No.	42 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007962AM24
RA File Number	03AX04004657 AM24
Licence No and Date	0311030163/15/01/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/24 dated 05/03/2024** against advance authorization **No.0311014263 dated 29/04/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

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

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

Case No.	43 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007963AM24
RA File Number	03AX04004676 AM24

Licence No and Date	0311030164/15/01/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/24 dated 05/03/2024 against advance authorization No.0311014263 dated 29/04/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	44 / NC/3/MEET/Mar/202324/26			
Case Status	Case Approved			
Party Name	HARMAN FINOCHEM LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024			
HQ File Number	HQRNORM APPLY 00007964AM24			
RA File Number	03AX04004677 AM24			
Licence No and Date	0311030165/15/01/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/24 dated 05/03/2024 against advance authorization No.0311014263 dated 29/04/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid	1.237 kg.

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

Case No.	45 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007970AM24
RA File Number	05AX04003290 AM24
Licence No and Date	0511023265/15/01/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jan/202324/21 dated 24/01/2024** against advance authorization **No.0511018851 dated 17/05/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tobramycin Inhalation Solution, 300mg/4ml (Having net content of 106.031 kg of Bulk drug (filling volume 4.35ml in each number))	1 Number	1	TOBRAMYCIN USP	306 mg.

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

Case No.	46 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024

and Date											
HQ File Number	HQRNORM APPLY 00007979AM24										
RA File Number	03AX04004700 AM24										
Licence No and Date	0311030205/16/01/2024										
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/24 dated 05/03/2024 against advance authorization No.0311014263 dated 29/04/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Sacubitril+Calcium (Sacubitril Calcium)</td> <td>1 kg.</td> <td>1</td> <td>2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)</td> <td>1.237 kg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.							

Case No.	47 / NC/3/MEET/Mar/202324/26								
Case Status	Case Approved								
Party Name	HARMAN FINOCHEM LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024								
HQ File Number	HQRNORM APPLY 00007980AM24								
RA File Number	03AX04004696 AM24								
Licence No and Date	0311030206/16/01/2024								
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/24 dated 05/03/2024 against advance authorization No.0311014263 dated 29/04/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					

Sacubitril+Calcium (Sacubitril Calcium)	1 kg.	1	2R,4S)-5-([1,1 -biphenyl]-4-yl)-4-(tert-butoxycarbonyl)amino)-2-methylpentanoic acid (BMPA)	1.237 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	48 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	REYAANSH HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00007997AM24
RA File Number	03AX04004636 AM24
Licence No and Date	0311030230/16/01/2024

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.
IMPACT SOLUTION FOR CATS 0.40 ML.(Each ml contains Imidacloprid 100 mg + Moxidectin 10 mg. Moxidectin consumed including wastages & overages :- 0.400 Kg. (Net content of Moxidectin is 0.3636 KGS))	90912 Numbers	1	Moxidectin	370.92 gm.
IMPACT SOLUTION FOR CATS 0.80 ML(Each ml contains Imidacloprid 100 mg + Moxidectin 10 mg. Moxidectin consumed including wastages & overages :- 1.400 Kg. (Net content of Moxidectin is 1.2727 KGS))	159093 Numbers	2	Moxidectin	1298.20 gm
IMPACT SOLUTION FOR DOGS 0.40 ML(Each ml contains Imidacloprid 100 mg + Moxidectin 25 mg. Moxidectin consumed including wastages & overages :- 1 Kg. (Net content of Moxidectin is 0.9091KGS))	90912 Numbers	3	Moxidectin	927.30 gm
IMPACT SOLUTION FOR DOGS 1 ML.(Each ml contains Imidacloprid 100 mg + Moxidectin 25 mg. Moxidectin	134550	4	Moxidectin	3431.025 gm.

consumed including wastages & overages :- 3.700 Kg. (Net content of Moxidectin is 3.3637 KGS))	Numbers			
IMPACT SOLUTION FOR DOGS 2.50 ML.(Each ml contains Imidacloprid 100 mg + Moxidectin 25 mg. Moxidectin consumed including wastages & overages :- 2.500 Kg. (Net content of Moxidectin is 2.2729 KGS))	36366 Numbers	5	Moxidectin	2318.33 gm.
IMPACT SOLUTION FOR DOGS 4 ML.(Each ml contains Imidacloprid 100 mg + Moxidectin 25 mg. Moxidectin consumed including wastages & overages :- 2 Kg. (Net content of Moxidectin is 1.8186 KGS))	18186 Numbers	6	Moxidectin	1854.972 gm.

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

Case No.	49 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	SAGA LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008014AM24
RA File Number	08AX04001772 AM24
Licence No and Date	0811010513/17/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	50 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	SANPRAS HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008015AM24
RA File Number	31AX04000283 AM24
Licence No and Date	3111003005/17/01/2024

Norms Committee Decision:

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

Case No.	51 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008036AM24
RA File Number	05AX04003341 AM24
Licence No and Date	0511023326/17/01/2024

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Sep/202324/14 dated 27/09/2023** against advance authorization **No.0511019931 dated 19/07/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Moxifloxacin HCL and Dexamethasone Sodium Phosphate Eye Drops 0.5%w/v, 0.1% w/v, 5ml((Each ml contain Moxifloxacin Base 5mg. equi. To Moxifloxacin HCL 5.45mg. & Dexamethasone Phosphate 1mg equi. To Dexamethasone Sodium Phosphate 1.1mg (Equi.to 1473.435gm Moxifloxacin HCL and 297.391gm Dexamethasone Sodium Phosphate Bulk Drug))	54071 Numbers	1	Moxifloxacin Hydrochloride	1547.09 gram
		2	Dexamethasone Sodium Phosphate	312.26 gram

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

Case No.	52 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008039AM24
RA File Number	03AX04004687 AM24
Licence No and Date	0311030266/18/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	53 / NC/3/MEET/Mar/202324/26			
Case Status	Case Approved			
Party Name	GLENFIN CHEMICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024			
HQ File Number	HQRNORM APPLY 00008040AM24			
RA File Number	03AX04004722 AM24			
Licence No and Date	0311030267/18/01/2024			
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:-				

Note: Yield of the reaction is less at initial stage, therefore, recommended on one time basis.

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

Case No.	54 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008057AM24
RA File Number	03AX04004728 AM24
Licence No and Date	0311030291/19/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	55 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ANNORA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008068AM24
RA File Number	09AX04000846 AM24
Licence No and Date	0911006469/19/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	56 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	CHEMIPRIME IMPEX PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024

and Date																				
HQ File Number	HQRNORM APPLY 00008089AM24																			
RA File Number	03AX04004810 AM24																			
Licence No and Date	0311030338/22/01/2024																			
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jan/202324/20 dated 18/01/2024 against advance authorization No.0311022361 dated 23/03/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Epocure HD 1618 (Cycloaliphatic amine)</td> <td rowspan="3">1 kg.</td> <td>1</td> <td>Epoxy Hardener</td> <td>0.5025 kg.</td> </tr> <tr> <td>2</td> <td>Benzyl Alcohol</td> <td>0.3015 kg.</td> </tr> <tr> <td>3</td> <td>Liquid Epoxy Resin</td> <td>0.201 kg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Epocure HD 1618 (Cycloaliphatic amine)	1 kg.	1	Epoxy Hardener	0.5025 kg.	2	Benzyl Alcohol	0.3015 kg.	3	Liquid Epoxy Resin	0.201 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
Epocure HD 1618 (Cycloaliphatic amine)	1 kg.	1	Epoxy Hardener	0.5025 kg.																
		2	Benzyl Alcohol	0.3015 kg.																
		3	Liquid Epoxy Resin	0.201 kg.																

Case No.	57 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008094AM24
RA File Number	08AX04001922 AM24
Licence No and Date	0811010550/22/01/2024
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	58 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008099AM24
RA File Number	03AX04004838 AM24
Licence No and Date	0311030345/22/01/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/23 dated 19/02/2024** against advance authorization **No.0311028216 dated 26/10/2023** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2,5-bis-(Tert-Nonyldithio)-1,3,4,-thiadizole (YALUB DM -113)	1 kg.	1	HYDRAZINE HYDRATE 80% (H.H)	0.134 kg.
		2	CARBON DISULPHIDE	0.3502 kg.
		3	TERT -NONYL MERCAPTAN (S-MERCAPTAN)	0.700 kg.

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

Case No.	59 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008112AM24
RA File Number	07AX04001679 AM24
Licence No and Date	0711010304/23/01/2024
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Dec/202324/17 dated 20/12/2023** against advance authorization **No.0711005589 dated 21/10/2022** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
LISINOPRIL 2.50 MG TABLETS(LISINOPRIL 2.5mg TABLETS (7.50KGS))	1 Number	1	LISINOPRIL DIHYDRATE BP/EP/IP/USP	2.55 mg/Tablet
LISINOPRIL 5.0 MG TABLETS(LISINOPRIL 5mg TABLETS (28.70 KGS))	1 Number	2	LISINOPRIL DIHYDRATE BP/EP/IP/USP	5.10 mg/Tablet
LISINOPRIL 10 MG TABLETS(LISINOPRIL 10 MG TABLETS (57.40 KGS))	1 Number	3	LISINOPRIL DIHYDRATE BP/EP/IP/USP	10.2 mg/Tablet
LISINOPRIL 20 MG TABLETS(LISINOPRIL 20 MG TABLETS (180.00 KGS))	1 Number	4	LISINOPRIL DIHYDRATE BP/EP/IP/USP	20.4 mg/Tablet

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

Case No.	60 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008141AM24
RA File Number	09AX04000959 AM24
Licence No and Date	0911006629/24/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	61 / NC/3/MEET/Mar/202324/26																
Case Status	Case Approved																
Party Name	YASHO INDUSTRIES LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024																
HQ File Number	HQRNORM APPLY 00008150AM24																
RA File Number	03AX04004874 AM24																
Licence No and Date	0311030426/24/01/2024																
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 rowspan="3">OCTYLATED DIPHENYLAMINE (OCD FLAKES/POWDER)</td><td rowspan="3">1 kg.</td><td>1</td><td>DIPHENYLAMINE</td><td>0.405 kg.</td></tr> <tr> <td>2</td><td>DI ISOBUTYLENE</td><td>0.622 kg.</td></tr> <tr> <td>3</td><td>ACTIVATED CLAY</td><td>0.100 kg.</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	OCTYLATED DIPHENYLAMINE (OCD FLAKES/POWDER)	1 kg.	1	DIPHENYLAMINE	0.405 kg.	2	DI ISOBUTYLENE	0.622 kg.	3	ACTIVATED CLAY	0.100 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
OCTYLATED DIPHENYLAMINE (OCD FLAKES/POWDER)	1 kg.	1	DIPHENYLAMINE	0.405 kg.													
		2	DI ISOBUTYLENE	0.622 kg.													
		3	ACTIVATED CLAY	0.100 kg.													

Case No.	62 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008152AM24
RA File Number	09AX04000948 AM24
Licence No and Date	0911006637/24/01/2024
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Feb/202324/23 dated 19/02/2024** against advance authorization **No.0911005810 dated 20/09/2023** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CARBIDOPA 12.5 MG LEVODOPA 50MG TABLETS	1 Number	1	CARBIDOPA	12.75 mg.
		2	LEVODOPA	51.00 mg

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

Case No.	63 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008154AM24
RA File Number	03AX04004736 AM24
Licence No and Date	0311030436/25/01/2024

Norms Committee Decision:

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

- i. **Step wise manufacturing process.**
- ii. **Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.**
- iii. **Complete technical details as per Annexure to Appendix 4E for chemical products.**
- iv. **Stoichiometric balance between import and export on molar basis.**
- v. **Details of indigenous input with quantity.**

Case No.	64 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008188AM24
RA File Number	34AX04000814 AM24
Licence No and Date	3411004545/29/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	65 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008190AM24
RA File Number	08AX04001949 AM24
Licence No and Date	0811010589/29/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	66 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	AROHEMA INGREDIENTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008195AM24
RA File Number	26AX04000076 AM24
Licence No and Date	2611001303/29/01/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jan/202324/21 dated 24/01/2024 against advance authorization No.2611001171 dated 13/10/2023 , 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.
AMBRETTOLIDE VEG	1 kg.	1	7-OCTENOL	1.999 kg.
		2	INHERENT UC 12 ME	2.69 kg.
		3	ULTRACAT	0.000089 kg.
		4	SNATCHCAT	0.000104 kg.
		5	GREEN CAT	Not imported.

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

Case No.	67 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008198AM24
RA File Number	30AX04000481 AM24
Licence No and Date	3011004726/29/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	68 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024

and Date	
HQ File Number	HQRNORM APPLY 00008210AM24
RA File Number	05AX04003445 AM24
Licence No and Date	0511023507/30/01/2024
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Chemical reaction of the process indicating Structural formula of reactants and products and molecular weight (without using abbreviation of chemicals name). Stage wise and also overall yield of the reactgio and Stoichiometric balance between import and export items on molar basis. Application/function of each chemical in the process with justification. Indigenous items to use in the process and accordingly to fill Annexure to Appendix-4E. Commercial value of the by-poroduct, if any.	

Case No.	69 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008214AM24
RA File Number	34AX04000788 AM24
Licence No and Date	3411004560/30/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	70 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008215AM24
RA File Number	34AX04000793 AM24
Licence No and Date	3411004561/30/01/2024
Norms Committee Decision:	

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

Certificate of Analysis (CoA) of import item from Foreign Supplier.

Case No.	71 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008239AM24
RA File Number	08AX04001964 AM24
Licence No and Date	0811010619/31/01/2024

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.
AMIKACIN SULFATE 500mg/2ml	1 Number	1	AMIKACIN SULFATE	715.81 mg.
AMIKACIN SULFATE 100mg/2ml	1 Number	2	AMIKACIN SULFATE	143.16 mg.

Note: RA may be clarified when the export item has already had a SION A-3646, which is published on 17.03.2016 vide Public Notice No. 64/2015-20 dated 17.03.2016, why the Advance Authorisation issued to the firm under para 4.07 of HBP Vol.1

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

Case No.	72 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024

and Date	
HQ File Number	HQRNORM APPLY 00008241AM24
RA File Number	05AX04003464 AM24
Licence No and Date	0511023530/31/01/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Aug/202223/6 dated 09/09/2022** against advance authorization **No.0511008191 dated 21/01/2022** , 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.
Budesonide Suspension For Inhalation , 0.125 mg / ml (2 ml Ampoule)(Budesonide Suspension For Inhalation , 0.125 mg /ml (2 ml Ampoule) (Each ml contains Budesonide 0.125 mg (Equivalent to 2.100 Kg of Bulk Drug))	8400000 Numbers	1	Budesonide	2.205 kg.
Budesonide Suspension For Inhalation , 0.25 mg / ml (2 ml Ampoule)(Budesonide Suspension For Inhalation , 0.25 mg / ml (2 ml Ampoule) (Each ml contains Budesonide 0.250 mg (Equivalent to 4.950 Kg. of Bulk Drug))	9900000 Numbers	2	Budesonide	5.198 kg.
Budesonide Suspension For Inhalation , 0.5 mg / ml (2 ml Ampoule)(Budesonide Suspension For Inhalation , 0.5 mg / ml (2 ml Ampoule) (Each ml contains Budesonide 0.5 mg (Equivalent to 2.400 Kg. of Bulk Drug) Total Bulk Drug Qty. 9.450Kg.))	2400000 Numbers	3	Budesonide	2.52 kg.

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

Case No.	73 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008252AM24

RA File Number	09AX04000962 AM24
Licence No and Date	0911006666/31/01/2024
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- i. Complete and Balanced chemical reactions, molar weight and percentage yield on molar basis, for each step. ii. Production/Consumption data for last three years duly certified by GST Authorities.	

Case No.	74 / NC/3/MEET/Mar/202324/26													
Case Status	Case Approved													
Party Name	LASENOR INDIA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024													
HQ File Number	HQRNORM APPLY 00008258AM24													
RA File Number	50AX04000096 AM24													
Licence No and Date	5011001267/31/01/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jan/202324/20 dated 18/01/2024 against advance authorization No.5011000524 dated 12/07/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Sunflower Lecithin Powder</td><td>1 MT.</td><td>1</td><td>Crude Sunflower Lecithin (Liquid form)</td><td>1.40 MT</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sunflower Lecithin Powder	1 MT.	1	Crude Sunflower Lecithin (Liquid form)	1.40 MT
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Sunflower Lecithin Powder	1 MT.	1	Crude Sunflower Lecithin (Liquid form)	1.40 MT										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	75 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	RUBICON RESEARCH PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008260AM24
RA File Number	03AX04004795 AM24
Licence No and Date	0311030581/31/01/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	76 / NC/3/MEET/Mar/202324/26																													
Case Status	Case Approved																													
Party Name	VEKO CARE PRIVATE LIMITED																													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024																													
HQ File Number	HQRNORM APPLY 00008268AM24																													
RA File Number	03AX04004982 AM24																													
Licence No and Date	0311030597/01/02/2024																													
Norms Committee Decision:																														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/23 dated 19/02/2024 against advance authorization No.3111002689 dated 05/10/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">TYLODOX GOLD WSP (Pack size 1 Kgs Jar)(Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)</td><td rowspan="2">1 Number</td><td>1</td><td>Tylosin Tartrate BP/USP /EP</td><td>0.101 kg.</td></tr><tr><td>3</td><td>Doxycycline Hyclate BP/EP/USP</td><td>0.202 kg.</td></tr><tr><td rowspan="2">TYLODOX GOLD WSP (Pack size 100 Gms sachet)(Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)</td><td rowspan="2">1 Number</td><td>2</td><td>Tylosin Tartrate BP/USP /EP</td><td>10.1 gm.</td></tr><tr><td>4</td><td>Doxycycline Hyclate BP/EP/USP</td><td>20.2 gm.</td></tr><tr><td>GENTADOX GOLD 100 / 200 (pack Size 1 Kgs Jar) (Each gram powder contains: Doxycycline Hyclate BP 200mg, Gentamycin Sulphate USP 100mg)</td><td>1 Number</td><td>5</td><td>Doxycycline Hyclate BP/EP/USP</td><td>0.202 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	TYLODOX GOLD WSP (Pack size 1 Kgs Jar)(Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)	1 Number	1	Tylosin Tartrate BP/USP /EP	0.101 kg.	3	Doxycycline Hyclate BP/EP/USP	0.202 kg.	TYLODOX GOLD WSP (Pack size 100 Gms sachet)(Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)	1 Number	2	Tylosin Tartrate BP/USP /EP	10.1 gm.	4	Doxycycline Hyclate BP/EP/USP	20.2 gm.	GENTADOX GOLD 100 / 200 (pack Size 1 Kgs Jar) (Each gram powder contains: Doxycycline Hyclate BP 200mg, Gentamycin Sulphate USP 100mg)	1 Number	5	Doxycycline Hyclate BP/EP/USP	0.202 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																										
TYLODOX GOLD WSP (Pack size 1 Kgs Jar)(Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)	1 Number	1	Tylosin Tartrate BP/USP /EP	0.101 kg.																										
		3	Doxycycline Hyclate BP/EP/USP	0.202 kg.																										
TYLODOX GOLD WSP (Pack size 100 Gms sachet)(Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)	1 Number	2	Tylosin Tartrate BP/USP /EP	10.1 gm.																										
		4	Doxycycline Hyclate BP/EP/USP	20.2 gm.																										
GENTADOX GOLD 100 / 200 (pack Size 1 Kgs Jar) (Each gram powder contains: Doxycycline Hyclate BP 200mg, Gentamycin Sulphate USP 100mg)	1 Number	5	Doxycycline Hyclate BP/EP/USP	0.202 kg.																										

GENTADOX GOLD 100 /200 (pack Size 100 Gms Sachet) (Each gram powder contains: Doxycycline Hyclate BP 200mg, Gentamycin Sulphate USP 100mg)	1 Number	6	Doxycycline Hyclate BP/EP/USP	20.2 gm.
NEODOX GOLD WSP (pack Size 1 Kgs Jar)(Each gram contains: Doxycycline Hyclate BP 100 mg Neomycin Sulfate BP 100 mg)	1 Number	7	Doxycycline Hyclate BP/EP/USP	0.101 kg.
NEODOX -GOLD WSP (pack Size 100 Gms Sachet) (Each gram contains: Doxycycline Hyclate BP 100 mg Neomycin Sulfate BP 100 mg)	1 Number	8	Doxycycline Hyclate BP/EP/USP	10.1 gm.

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

Case No.	77 / NC/3/MEET/Mar/202324/26													
Case Status	Case Approved													
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024													
HQ File Number	HQRNORM APPLY 00008271AM24													
RA File Number	08AX04001973 AM24													
Licence No and Date	0811010634/01/02/2024													
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>Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)</td><td>1 Number</td><td>1</td><td>Tranexamic acid (Injectable grade, US FDA approved)</td><td>1.05 gm/100 ml Vial</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)	1 Number	1	Tranexamic acid (Injectable grade, US FDA approved)	1.05 gm/100 ml Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)	1 Number	1	Tranexamic acid (Injectable grade, US FDA approved)	1.05 gm/100 ml Vial										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	78 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008274AM24
RA File Number	05AX04003478 AM24
Licence No and Date	0511023580/01/02/2024
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- i. Step wise manufacturing process. ii. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. iii. Complete technical details as per Annexure to Appendix 4E for chemical products. iv. Stoichiometric balance between import and export on molar basis. v. Details of indigenous input with quantity.	

Case No.	79 / NC/3/MEET/Mar/202324/26										
Case Status	Case Approved										
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024										
HQ File Number	HQRNORM APPLY 00008275AM24										
RA File Number	03AX04004861 AM24										
Licence No and Date	0311030600/01/02/2024										
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>Fluorouracil INJ BP 1000 MG/20 ML</td><td>1 Vial</td><td>1</td><td>Fluorouracil IP/BP</td><td>1050 mg/Vial</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Fluorouracil INJ BP 1000 MG/20 ML	1 Vial	1	Fluorouracil IP/BP	1050 mg/Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Fluorouracil INJ BP 1000 MG/20 ML	1 Vial	1	Fluorouracil IP/BP	1050 mg/Vial							

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

Case No.	80 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008278AM24
RA File Number	08AX04001950 AM24
Licence No and Date	0811010645/01/02/2024
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Certificate of Analysis (CoA) of import item from Foreign Supplier.	

Case No.	81 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	PRASOL CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
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 firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity.	

Case No.	82 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008307AM24
RA File Number	09AX04000889 AM24
Licence No and Date	0911006687/02/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	83 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	SYSTOCHEM LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008313AM24
RA File Number	05AX04003564 AM24
Licence No and Date	0511023623/02/02/2024
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:-	
Vial size of export product in line to DML.	

Case No.	84 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008315AM24
RA File Number	05AX04003539 AM24

Licence No and Date	0511023621/02/02/2024													
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jan/202324/21 dated 24/01/2024 against advance authorization No.0511018894 dated18/05/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml</td> <td>1 Vial</td> <td>1</td> <td>Brinzolamide Micronized Sterile</td> <td>51.00 mg/Vial</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.	Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml	1 Vial	1	Brinzolamide Micronized Sterile	51.00 mg/Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml	1 Vial	1	Brinzolamide Micronized Sterile	51.00 mg/Vial										

Case No.	85 / NC/3/MEET/Mar/202324/26													
Case Status	Case Approved													
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024													
HQ File Number	HQRNORM APPLY 00008334AM24													
RA File Number	03AX04005004 AM24													
Licence No and Date	0311030668/05/02/2024													
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>ALVERINE CITRATE 120 MG CAPSULES</td> <td>1 Number</td> <td>1</td> <td>Alverine Citrate</td> <td>122.4 mg./Capsule</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ALVERINE CITRATE 120 MG CAPSULES	1 Number	1	Alverine Citrate	122.4 mg./Capsule
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
ALVERINE CITRATE 120 MG CAPSULES	1 Number	1	Alverine Citrate	122.4 mg./Capsule										

ALVERINE CITRATE 60 MG CAPSULES	1 Number	2	Alverine Citrate	61.2 mg./Capsule
RA concerned may take further necessary action as per above decision of NC.				

Case No.	86 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008337AM24
RA File Number	08AX04001983 AM24
Licence No and Date	0811010681/05/02/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Sep/202324/14 dated 27/09/2023** against advance authorization **No.0811008938 dated 30/07/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CLOZAPINE TABLETS 100 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE B.P 100 MG NET CONTENT OF CLOZAPINE BP SHOULD NOT BE LESS THAN 39.000 KGS. IN EXPORT ITEM)	1 Number	1	CLOZAPINE BP	102.00 mg/tablet

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

Case No.	87 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred

Party Name	LOZEN PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008339AM24
RA File Number	03AX04004941 AM24
Licence No and Date	0311030679/05/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	88 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	SPC LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008350AM24
RA File Number	34AX04000824 AM24
Licence No and Date	3411004576/05/02/2024
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis. Details of indigenous input with quantity.	

Case No.	89 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008367AM24
RA File Number	52AX04000336 AM24
Licence No and Date	5211007280/06/02/2024

Norms Committee Decision:

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

1. **Complete Chemical reaction starting from raw materials, stage wise yield and overall yield.**
2. **Indigenous items to use in thr process and accordingly to file Annexure to Appendix-4E.**
3. **Stoichiometric material balance on a molar basis, indicating requiremntn of raw materials.**
4. **End use of export product**

Case No.	90 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008368AM24
RA File Number	09AX04000955 AM24
Licence No and Date	0911006697/06/02/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Dec/202324/17 dated 20/12/2023** against advance authorization **No.0911001093 dated 23/06/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tobramycin for Inhalation solution 60 mg / ml (300 mg / 5 ml)	1 Number	1	Tobramycin Sulfate	466.49 mg./Vial
Tobramycin for Inhalation solution 75 mg / ml (300 mg / 4 ml)	1 Number	2	Tobramycin Sulfate	466.49 mg./Vial

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

Case No.	91 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008379AM24
RA File Number	03AX04004853 AM24
Licence No and Date	0311030712/06/02/2024

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 Cromoglicate (Allercrom , Allerfix, Murine Hayfever) Eye Drops 2% w/v 10 ML((EACH 10 ML VIAL CONTAINS SODIUM CROMOGLICATE 0.2 GM NET WT OF BULK 28.830 KGS))	1 Vial	1	SODIUM CROMOGLICATE	0.204 gm./ 10 ml. vial
Cromolyn Sodium Eye Drops 5 ML (Allercrom Eye Drops)((EACH 5 ML VIAL CONTAINS SODIUM CROMOGLICATE 0.1 GM NET WT OF BULK 10.175 KGS))	1 Vial	2	SODIUM CROMOGLICATE	0.102 gm./ 5 ml. vial

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

Case No.	92 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	UNI MEDICOLABS
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008382AM24
RA File Number	05AX04003540 AM24
Licence No and Date	0511023728/06/02/2024

Norms Committee Decision:

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

Case No.	93 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008383AM24
RA File Number	07AX04001749 AM24
Licence No and Date	0711010420/06/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	94 / NC/3/MEET/Mar/202324/26													
Case Status	Case Approved													
Party Name	ENCEE AROMATICS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024													
HQ File Number	HQRNORM APPLY 00008402AM24													
RA File Number	32AX04000657 AM24													
Licence No and Date	3211006285/07/02/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Sep/202223/8 dated 23/09/2022 against advance authorization No.3211001926 dated 12/11/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Enamber / Kephalis / Tetrambrone</td><td rowspan="2">1 kg.</td><td>1</td><td>Triethyl Orthoformate</td><td>2.400 kg.</td></tr><tr><td>2</td><td>Mesityl Oxide</td><td>2.700 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Enamber / Kephalis / Tetrambrone	1 kg.	1	Triethyl Orthoformate	2.400 kg.	2	Mesityl Oxide	2.700 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Enamber / Kephalis / Tetrambrone	1 kg.	1	Triethyl Orthoformate	2.400 kg.										
		2	Mesityl Oxide	2.700 kg.										

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

Case No.	95 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	ARIHANTANAM LIFECARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008403AM24
RA File Number	52AX04000332 AM24
Licence No and Date	5211007299/07/02/2024

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.
LUMEFANTRINE	5754 kg.	1	(DIBUTYLAMINE METHYL)-2,7-DICHLORO-4-FLUOREN METHANOL (DBA)	5000 kg.

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

Case No.	96 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008405AM24
RA File Number	03AX04004186 AM24
Licence No and Date	0311030768/07/02/2024

Norms Committee Decision:

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

- i. End use of the export product.**
- ii. Step wise manufacturing process.**
- iii. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.**
- iv. Complete technical details as per Annexure to Appendix 4E for chemical products.**
- v. Stoichiometric balance between import and export on molar basis.**
- vi. Details of indigenous input with quantity.**

Case No.	97 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008409AM24
RA File Number	03AX04004239 AM24
Licence No and Date	0311030769/07/02/2024

Norms Committee Decision:

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

- i. End use of the export product.**
- ii. Step wise manufacturing process.**
- iii. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.**
- iv. Complete technical details as per Annexure to Appendix 4E for chemical products.**
- v. Stoichiometric balance between import and export on molar basis.**
- vi. Details of indigenous input with quantity.**

Case No.	98 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008420AM24
RA File Number	07AX04001738 AM24

Licence No and Date	0711010455/08/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	99 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008429AM24
RA File Number	05AX04003525 AM24
Licence No and Date	0511023848/08/02/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jan/202324/21 dated 24/01/2024** against advance authorization **No.0511021195 dated 27/09/2023** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRI ETHYL CITRATE (TEC) (TRI ETHYL CITRATE (TEC) (PACKED IN 800 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES (6,800.000 KGS.WITHOUT WASTAGE)) (EACH DRUM SHALLWEIGHT 8.5KG 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 = 7,140.000 KGS.)	Relevant, as per packing policy and General Notes.

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

Case No.	100 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008436AM24
RA File Number	52AX04000323 AM24
Licence No and Date	5211007312/08/02/2024
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Complete Chemical reaction starting from raw materials, stage wise yield and overall yield. 2. Indigenous items to use in the process and accordingly to fill Annexure to Appendix-4E. 3. Stoichiometric material balance on a molar basis, indicating requirement of raw material. 4. End use of export product	

Case No.	101 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008450AM24
RA File Number	03AX04005000 AM24
Licence No and Date	0311030997/09/02/2024
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	102 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008464AM24
RA File Number	05AX04003559 AM24
Licence No and Date	0511023876/09/02/2024

Norms Committee Decision:

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

1. **Chemical reaction of the process indicating Structural formula of reactants and products and molecular weight (without using abbreviation of chemicals name).**
2. **Stage wise and also overall yield of the reactgio and Stoichiometric balance between import and export items on molar basis.**
3. **Application/function of each chemical in the process with justification.**
4. **Indigenous items to use in the process and accordingly to fill Annexure to Appendix-4E.**
5. **Commercial value of the by-product, if any.**

Case No.	103 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008469AM24
RA File Number	05AX04003618 AM24
Licence No and Date	0511023881/09/02/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jan/202324/21 dated 24/01/2024** against advance authorization **No.0511021940 dated 07/11/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Atropine Sulfate Ophthalmic Solution USP, 1% 2 ml(Having net content of 2.40 kg of Bulk drug (filling volume 2.32 ml in each number))	1 Number	1	ATROPINE SULPHATE	20.40 mg.
Atropine Sulfate Ophthalmic Solution USP, 1% 5 ml(Having net content of 4.80 kg of Bulk drug (filling volume 5.61 ml in each number))	1 Number	2	ATROPINE SULPHATE	51.00 mg.
Atropine Sulfate Ophthalmic Solution USP, 1% 15 ml(Having net content of 3.60 kg of Bulk drug (filling volume 15.91 ml in each number))	1 Number	3	ATROPINE SULPHATE	153.0 mg

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

Case No.	104 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ELPPE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008471AM24
RA File Number	03AX04004959 AM24
Licence No and Date	0311031032/09/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	105 / NC/3/MEET/Mar/202324/26										
Case Status	Case Approved										
Party Name	PIRAMAL PHARMA LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024										
HQ File Number	HQRNORM APPLY 00008498AM24										
RA File Number	03AX04005150 AM24										
Licence No and Date	0311031086/12/02/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Sep/202324/14 dated 27/09/2023 against advance authorization No.0311026365 dated 16/08/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Atorvastatin Calcium Tablets USP 10mg ((Net Content of Import Sr. No. 1 is 5.137 kgs, Sr.</td><td>1 Number Tablet</td><td>1</td><td>Atorvastatin Calcium Propylene Glycol Solvate USP</td><td>11.4415 mg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Atorvastatin Calcium Tablets USP 10mg ((Net Content of Import Sr. No. 1 is 5.137 kgs, Sr.	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.4415 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Atorvastatin Calcium Tablets USP 10mg ((Net Content of Import Sr. No. 1 is 5.137 kgs, Sr.	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.4415 mg							

No. 2 is 29.060 kg, Sr. No. 3 is 8.122 kg, Sr. No. 4 is 5050 Nos.))		2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg.
		3	Calcium Acetate	18.049 mg.
		4	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy and General Notes.
Atorvastatin Calcium Tablets USP 20 mg ((Net Content of Import Sr. No. 1 is 102.735 kgs, Sr. No. 2 is 582.422 kg, Sr. No. 3 is 162.405 kg, Sr. No. 4 is 50500 Nos.))	1 Number Tablet	5	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg.
		6	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427 mg.
		7	Calcium Acetate	36.090 mg.
		8	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy and General Notes.
Atorvastatin Calcium Tablets USP 40mg ((Net Content of Import Sr. No. 1 is 1436.243 kgs, Sr. No. 2 is 8129.520 kg, Sr. No. 3 is 2266.835 kg, Sr. No. 4 is 353500 Nos.))	1 Number Tablet	9	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg.
		10	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08 mg.
		11	Calcium Acetate	71.963 mg.
		12	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy and General Notes.
Atorvastatin Calcium Tablets USP 80mg ((Net Content of Import Sr. No. 1 is 4104.000 kgs, Sr. No. 2 is 23319.720 kg, Sr. No. 3 is 6521.805 kg, Sr. No. 4 is 505000 Nos.))	1 Number Tablet	13	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg.
		14	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg.
		15	Calcium Acetate	144.929 mg.

		16	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant, as per packing policy and General Notes.
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Note: The above norms are valid only for subject to fulfillment of following conditions:-

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

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

Case No.	106 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	SMS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008513AM24
RA File Number	09AX04000992 AM24
Licence No and Date	0911006731/12/02/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Sep/202324/14 dated 27/09/2023** against advance authorization **No.0911005461 dated 21/07/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SITAGLIPTIN HYDROCHLORIDE	1 kg.	1	2,4,5 TRIFLUOROPHENYLACETIC ACID	1.146 kg.
		2	MELDRUM ACID	0.88 kg.

		3	3-(TERIFLUOROMETHYL)-5,6,7,8-TETRAHYDRI-[1,2,4] TRIAZOLO[4,3-a] PYRAZINE HYDROCHLORIDE	0.75 kg.
		4	DI-TERTIARY BUTYL DICARBONATE (DIBOC)	1.50 kg.
		5	TETRAHYDROFURAN	2.56 kg.
		6	ISO PROPYL ALCOHOL	3.75 kg.
		7	METHANOL	7.77 kg.
		8	N-HEPTANE	1.80 kg.
		9	TERTIARY BUTANOL (T-BUTANOL)	2.17 kg.
		10	R-(+)-Alpha-Phenylethylamine	1.00 kg.
		11	SODIUM BOROHYDRIDE	0.30 kg.
		12	ACETONITRILE	1.14 kg.
		RA concerned may take further necessary action as per above decision of NC.		

Case No.	107 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	SMILAX LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008518AM24
RA File Number	09AX04000984 AM24
Licence No and Date	0911006732/12/02/2024
Norms Committee Decision:	

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

Case No.	108 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	CATION PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008519AM24
RA File Number	52AX04000341 AM24
Licence No and Date	5211007357/12/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	109 / NC/3/MEET/Mar/202324/26										
Case Status	Case Approved										
Party Name	STERILE INDIA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024										
HQ File Number	HQRNORM APPLY 00008530AM24										
RA File Number	05AX04003214 AM24										
Licence No and Date	0511023924/13/02/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Aug/202324/11 dated 22/08/2023 against advance authorization No.0510414006 dated 16/04/2020 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed</th></tr><tr><td>CEFEPIME FOR INJECTION</td><td>1 kg.</td><td>1</td><td>CEFEPIME HCL (NON STERILE)</td><td>0.655 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	CEFEPIME FOR INJECTION	1 kg.	1	CEFEPIME HCL (NON STERILE)	0.655 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed							
CEFEPIME FOR INJECTION	1 kg.	1	CEFEPIME HCL (NON STERILE)	0.655 kg.							

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

Case No.	110 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008531AM24
RA File Number	08AX04002041 AM24
Licence No and Date	0811010749/13/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	111 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008554AM24
RA File Number	05AX04003657 AM24
Licence No and Date	0511023947/13/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	112 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008559AM24
RA File Number	03AX04004580 AM24

Licence No and Date	0311031163/14/02/2024
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- - End use of the export product. - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity.	

Case No.	113 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008564AM24
RA File Number	03AX04005181 AM24
Licence No and Date	0311031166/14/02/2024
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	114 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008566AM24
RA File Number	05AX04003666 AM24
Licence No and Date	0511023953/14/02/2024
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	115 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	BASIL DRUGS AND PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008570AM24
RA File Number	03AX04005041 AM24
Licence No and Date	0311031186/14/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	116 / NC/3/MEET/Mar/202324/26																
Case Status	Case Approved																
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024																
HQ File Number	HQRNORM APPLY 00008572AM24																
RA File Number	09AX04000977 AM24																
Licence No and Date	0911006753/14/02/2024																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Sep/202324/14 dated 27/09/2023 against advance authorization No.0911005617 dated 10/08/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<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">GCLE(7- PHENYLACETAMIDEO- 3-CHLOROMETHYLCEPHALOSPORANIC ACID PARA METHOXY BENZYL ESTER) (WHITE CRYSTALLINE POWDER)</td><td rowspan="3">1 kg.</td><td>1</td><td>PENICILLIN G POTASSIUM FIRST CRYSTAL</td><td>1.375 kg.</td></tr><tr><td>2</td><td>ACETONE</td><td>1.971 kg.</td></tr><tr><td>3</td><td>METHYLENE CHLORIDE MDC</td><td>3.29 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	GCLE(7- PHENYLACETAMIDEO- 3-CHLOROMETHYLCEPHALOSPORANIC ACID PARA METHOXY BENZYL ESTER) (WHITE CRYSTALLINE POWDER)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg.	2	ACETONE	1.971 kg.	3	METHYLENE CHLORIDE MDC	3.29 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
GCLE(7- PHENYLACETAMIDEO- 3-CHLOROMETHYLCEPHALOSPORANIC ACID PARA METHOXY BENZYL ESTER) (WHITE CRYSTALLINE POWDER)	1 kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg.													
		2	ACETONE	1.971 kg.													
		3	METHYLENE CHLORIDE MDC	3.29 kg.													

		4	2 MERCAPTO BENZO THIAZLOLE MBT	0.511 kg.
		5	METHANOL	1.971 kg.

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

Case No.	117 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008576AM24
RA File Number	03AX04005212 AM24
Licence No and Date	0311031193/14/02/2024

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.
Triisodecyl Phosphite((TDP))	1 kg.	1	PHENOL	0.06 kg.
		2	ISODECYL ALCOHOL OR 2 PROPYL HEPTANOL	0.98 kg.
		3	YELLOW PHOSPHORUS	0.06 kg.

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

Case No.	118 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	SUPRIYA LIFESCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008592AM24
RA File Number	03AX04005187 AM24
Licence No and Date	0311031241/15/02/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Dec/202324/17 dated 20/12/2023** against advance authorization **No.0311028054 dated 19/10/2023**, 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.
RIBOFLAVIN SODIUM PHOSPHATE HYDRATE EP 11.2	1 kg.	1	VITAMIN B2 OR RIBOFLAVIN	1.10 kg.
		2	PYRIDINE	2.00 kg.
		3	ACETONITRILE	1.73 kg.
		4	PHOSPHORUS OXYCHLORIDE	2.00 kg.

Note: Above norms are for EP 11.2 grade only. No interchangeable of grade is permitted.

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

Case No.	119 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008594AM24
RA File Number	05AX04003543 AM24

Licence No and Date	0511023989/15/02/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Nov/202324/12 dated 18/11/2022 against advance authorization No.0511010960 dated 11/03/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table 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>Ceftriaxone Sodium Sterile</td> <td>1 kg.</td> <td>1</td> <td>Ceftriaxone Sodium Non Sterile</td> <td>1.04 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ceftriaxone Sodium Sterile	1 kg.	1	Ceftriaxone Sodium Non Sterile	1.04 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Ceftriaxone Sodium Sterile	1 kg.	1	Ceftriaxone Sodium Non Sterile	1.04 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	120 / NC/3/MEET/Mar/202324/26																
Case Status	Case Approved																
Party Name	AMI ORGANICS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024																
HQ File Number	HQRNORM APPLY 00008597AM24																
RA File Number	52AX04000349 AM24																
Licence No and Date	5211007412/15/02/2024																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.4/82-ALC4/2018 dated 19/06/2018 against advance authorization No.5210042461 dated 22/12/2017, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1,2,4 - TRIAZOLO (4,3-a) PYRIDIN -3 (2H) - ONE - 98% MIN.</td> <td rowspan="2">1 kg.</td> <td>1</td> <td>SEMICARBAZIDE HCL - 99% MIN</td> <td>2.422 kg.</td> </tr> <tr> <td>2</td> <td>2-CHLORO PYRIDINE</td> <td>1.14 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	1,2,4 - TRIAZOLO (4,3-a) PYRIDIN -3 (2H) - ONE - 98% MIN.	1 kg.	1	SEMICARBAZIDE HCL - 99% MIN	2.422 kg.	2	2-CHLORO PYRIDINE	1.14 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
1,2,4 - TRIAZOLO (4,3-a) PYRIDIN -3 (2H) - ONE - 98% MIN.	1 kg.	1	SEMICARBAZIDE HCL - 99% MIN	2.422 kg.													
		2	2-CHLORO PYRIDINE	1.14 kg.													

		3	ETHYLENE GLYCOL MONOETHYL ETHER/2-ETHOXY ETHANOL	1.20 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	121 / NC/3/MEET/Mar/202324/26													
Case Status	Case Approved													
Party Name	TIDE INDUSTRIES													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024													
HQ File Number	HQRNORM APPLY 00008605AM24													
RA File Number	34AX04000854 AM24													
Licence No and Date	3411004626/16/02/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.15/82-ALC4/2018 dated 22/03/2019 against advance authorization No.3410044015 dated 04/04/2018 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Aldehyde C10(Capric Aldehyde)</td><td>1 kg.</td><td>1</td><td>Fatty Alcohol C10</td><td>1.40 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Aldehyde C10(Capric Aldehyde)	1 kg.	1	Fatty Alcohol C10	1.40 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Aldehyde C10(Capric Aldehyde)	1 kg.	1	Fatty Alcohol C10	1.40 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	122 / NC/3/MEET/Mar/202324/26			
Case Status	Case Deferred			
Party Name	YELLOWSTONE FINE CHEMICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024			
HQ File Number	HQRNORM APPLY 00008613AM24			

RA File Number	03AX04005249 AM24
Licence No and Date	0311031269/16/02/2024
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- i. Molecular weight of export product. ii. Stoichiometric Balance with percentage of yield on molar basis to arrive at the quantity of raw material asked.	

Case No.	123 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008616AM24
RA File Number	03AX04005267 AM24
Licence No and Date	0311031276/16/02/2024
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	124 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008617AM24
RA File Number	03AX04005241 AM24
Licence No and Date	0311031277/16/02/2024
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.
INDAPAMIDE 2.5MG TABLETS	1 Number	1	Indapamide	2.55 mg./Tablet

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

Case No.	125 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008618AM24
RA File Number	03AX04005219 AM24
Licence No and Date	0311031282/16/02/2024
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:-	

Case No.	126 / NC/3/MEET/Mar/202324/26			
Case Status	Case Approved			
Party Name	CDYMAX (INDIA) PHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024			

HQ File Number	HQRNORM APPLY 00008638AM24			
RA File Number	07AX04001746 AM24			
Licence No and Date	0711010558/19/02/2024			
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:-				

Case No.	127 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008643AM24
RA File Number	05AX04003613 AM24
Licence No and Date	0511024042/19/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	128 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	PRASHI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008647AM24
RA File Number	03AX04005005 AM24

Licence No and Date	0311031320/19/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	129 / NC/3/MEET/Mar/202324/26													
Case Status	Case Approved													
Party Name	FDC LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024													
HQ File Number	HQRNORM APPLY 00008651AM24													
RA File Number	03AX04005314 AM24													
Licence No and Date	0311031329/20/02/2024													
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>GENTAMICIN EYE/EAR DROPS 10 ML ((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.030GM NET WT OF BULK DRUG IS 4.140 KGS))</td><td>138000 Vials</td><td>1</td><td>GENTAMICIN SULPHATE</td><td>5.072 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	GENTAMICIN EYE/EAR DROPS 10 ML ((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.030GM NET WT OF BULK DRUG IS 4.140 KGS))	138000 Vials	1	GENTAMICIN SULPHATE	5.072 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
GENTAMICIN EYE/EAR DROPS 10 ML ((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.030GM NET WT OF BULK DRUG IS 4.140 KGS))	138000 Vials	1	GENTAMICIN SULPHATE	5.072 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	130 / NC/3/MEET/Mar/202324/26			
Case Status	Case Deferred			
Party Name	GLOBAL CALCIUM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024			

HQ File Number	HQRNORM APPLY 00008671AM24
RA File Number	07AX04001818 AM24
Licence No and Date	0711010595/21/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	131 / NC/3/MEET/Mar/202324/26																		
Case Status	Case Approved																		
Party Name	GLOBAL CALCIUM PRIVATE LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024																		
HQ File Number	HQRNORM APPLY 00008672AM24																		
RA File Number	07AX04001823 AM24																		
Licence No and Date	0711010596/21/02/2024																		
Norms Committee Decision:																			
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No.0711003904 dated 04/05/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																			
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>MAGNESIUM PIDOLATE (Eur.Ph)</td><td>1 MT</td><td>1</td><td>L-PYROGLUTAMIC ACID</td><td>0.90 MT</td></tr><tr><td>CALCIUM PIDOLATE</td><td>1 MT</td><td>2</td><td>L-PYROGLUTAMIC ACID</td><td>0.82 MT</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MAGNESIUM PIDOLATE (Eur.Ph)	1 MT	1	L-PYROGLUTAMIC ACID	0.90 MT	CALCIUM PIDOLATE	1 MT	2	L-PYROGLUTAMIC ACID	0.82 MT
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
MAGNESIUM PIDOLATE (Eur.Ph)	1 MT	1	L-PYROGLUTAMIC ACID	0.90 MT															
CALCIUM PIDOLATE	1 MT	2	L-PYROGLUTAMIC ACID	0.82 MT															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	132 / NC/3/MEET/Mar/202324/26
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Case Status	Case Deferred
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008680AM24
RA File Number	08AX04002108 AM24
Licence No and Date	0811010830/21/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	133 / NC/3/MEET/Mar/202324/26													
Case Status	Case Approved													
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024													
HQ File Number	HQRNORM APPLY 00008681AM24													
RA File Number	08AX04002104 AM24													
Licence No and Date	0811010831/21/02/2024													
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>Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)</td><td>1 Number</td><td>1</td><td>Tranexamic acid (Injectable grade, US FDA approved)</td><td>1.05 gm/100 ml Vial</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)	1 Number	1	Tranexamic acid (Injectable grade, US FDA approved)	1.05 gm/100 ml Vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Tranexamic Acid in 0.7% Sodium Chloride Injection 1,000 mg per 100 mL (10 mg/mL)	1 Number	1	Tranexamic acid (Injectable grade, US FDA approved)	1.05 gm/100 ml Vial										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	134 / NC/3/MEET/Mar/202324/26
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Case Status	Case Deferred
Party Name	SPAR PHARMA LLP
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008685AM24
RA File Number	09AX04000988 AM24
Licence No and Date	0911006814/21/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	135 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008687AM24
RA File Number	03AX04005332 AM24
Licence No and Date	0311031376/21/02/2024
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:-	

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

Case No.	136 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008696AM24
RA File Number	03AX04005309 AM24
Licence No and Date	0311031390/22/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	137 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	HIND PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008700AM24
RA File Number	56AX04000681 AM24
Licence No and Date	5611002746/22/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	138 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008716AM24
RA File Number	05AX04003777 AM24

Licence No and Date	0511024122/23/02/2024
Norms Committee Decision:	
The committee considered the case as per agenda and it was decided to fix ad-hoc norms as per SION A-412.	

Case No.	139 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008718AM24
RA File Number	03AX04005330 AM24
Licence No and Date	0311031439/23/02/2024
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Chemical name of SYNPERONIC T/1301-LQ-(CQ) and: Primol 352 and its function in the reaction and to enclosed the catalogue/literature. 2. Calculation to arrive the quantity of inputs, giving stage wise and overall yield of the reaction. 3. To fill Annexure to Appendix-4E giving indigenous items also to use.	

Case No.	140 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008744AM24
RA File Number	08AX04002112 AM24
Licence No and Date	0811010864/26/02/2024
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.
MEROPENEM FOR INJECTION 500MG (Meropenem 500mg Powder for Solution for Injection or Infusion. Each vial contains Active Pharmaceutical Ingredients Meropenem Trihydrate Eqv. to Meropenem Anhydrous 500mg Excipients: Anhydrous Sodium Carbonate 104mg, Equivalent to 45.1mg of Sodium)	1 Number	1	STERILE MIXTURE OF MEROPENEM AND SODIUM CARBONATE	0.645 gm/500 mg Injection
MEROPENEM FOR INJECTION 1gm (Meropenem 1.0 GM Powder for Solution for Injection or Infusion. Each vial contains Active Pharmaceutical Ingredients Meropenem Trihydrate Eqv. To Meropenem Anhydrous 1000mg Excipients: Anhydrous Sodium Carbonate 208mg, Equivalent to 90.2mg of Sodium)	1 Number	2	STERILE MIXTURE OF MEROPENEM AND SODIUM CARBONATE	1.29 gm /1gm Injection

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

Case No.	141 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008748AM24
RA File Number	09AX04001052 AM24
Licence No and Date	0911006828/26/02/2024
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.
CARBIDOPA 12.5 MG LEVODOPA 50MG TABLETS	1 Number	1	CARBIDOPA	12.75 mg/Tablet
		2	LEVODOPA	51.00 mg/Tablet

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

Case No.	142 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	MEDICLONE HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008751AM24
RA File Number	04AX04001035 AM24
Licence No and Date	0411006998/26/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	143 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	EAST AFRICAN INDIA OVERSEAS
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008754AM24
RA File Number	05AX04003662 AM24
Licence No and Date	0511024074/26/02/2024
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.
CEFIPRIN 200 TABLET(CEFIXIME 200 MG TABLET (PACK SIZE - 1 X 10'S))	1 Number	1	CEFIXIME	204.00 mg / Tablet
CEFIPRIN 400 TABLET(CEFIXIME 400 MG TABLET (PACK SIZE - 1 X 10'S))	1 Number	2	CEFIXIME	408 mg / Tablet
VIREXIM 400 CAPSULE(CEFIXIME 400 MG CAPSULE (PACK SIZE - 10 X 10'S))	1 Number	3	CEFIXIME	408 mg / Capsule

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

Case No.	144 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	EAST AFRICAN INDIA OVERSEAS
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008755AM24
RA File Number	05AX04003663 AM24
Licence No and Date	0511023926/26/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	145 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008761AM24
RA File Number	03AX04005401 AM24
Licence No and Date	0311031503/27/02/2024
Norms Committee Decision:	

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

Case No.	146 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	S KANT CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008762AM24
RA File Number	03AX04005393 AM24
Licence No and Date	0311031505/27/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	147 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008765AM24
RA File Number	03AX04005326 AM24
Licence No and Date	0311031507/27/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	148 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008771AM24
RA File Number	03AX04005218 AM24

Licence No and Date	0311031522/27/02/2024			
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:-				

Case No.	149 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008773AM24
RA File Number	08AX04002087 AM24
Licence No and Date	0811010888/27/02/2024
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	150 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008780AM24

RA File Number	03AX04005442 AM24
Licence No and Date	0311031542/27/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	151 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008783AM24
RA File Number	03AX04005399 AM24
Licence No and Date	0311031475/28/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	152 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008792AM24
RA File Number	08AX04002148 AM24
Licence No and Date	0811010899/28/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	153 / NC/3/MEET/Mar/202324/26
Case Status	Case Approved
Party Name	UMEDICA LABORATORIES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024													
HQ File Number	HQRNORM APPLY 00008795AM24													
RA File Number	03AX04005051 AM24													
Licence No and Date	0311031566/28/02/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting NoNC/3/MEET/Apr/202324/1 dated 28/04/2023 against advance authorization No.0311019954 dated 13/12/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Oxcarbazepine USP/BP/EP/IH</td><td>1 kg.</td><td>1</td><td>10-Methoxy Iminostilbene</td><td>1.10 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Oxcarbazepine USP/BP/EP/IH	1 kg.	1	10-Methoxy Iminostilbene	1.10 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Oxcarbazepine USP/BP/EP/IH	1 kg.	1	10-Methoxy Iminostilbene	1.10 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	154 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008801AM24
RA File Number	03AX04005270 AM24
Licence No and Date	0311031579/28/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	155 / NC/3/MEET/Mar/202324/26			
Case Status	Case Deferred			
Party Name	MAXMED LIFE SCIENCES PRIVATE LIMITED			
Meeting Number	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024			

and Date	
HQ File Number	HQRNORM APPLY 00008802AM24
RA File Number	05AX04003602 AM24
Licence No and Date	0511024076/28/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	156 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008814AM24
RA File Number	05AX04003827 AM24
Licence No and Date	0511024211/29/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	157 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008824AM24
RA File Number	34AX04000861 AM24
Licence No and Date	3411004655/29/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	158 / NC/3/MEET/Mar/202324/26
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Case Status	Case Deferred
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008826AM24
RA File Number	03AX04005194 AM24
Licence No and Date	0311031599/29/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	159 / NC/3/MEET/Mar/202324/26
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202324/ 26 and 22/03/2024
HQ File Number	HQRNORM APPLY 00008831AM24
RA File Number	08AX04002140 AM24
Licence No and Date	0811010931/29/02/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	