



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

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(DES - III SECTION)**MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Dec/202324/19**DATED:** 05/01/2024Please 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.

Meeting No. NC/3/MEET/Dec/202324/19 dated 05/01/2024 of Norms Committee - III for the year 2023-24 was held on 05/01/2024 under the Chairmanship of Rajiv Soni ,Joint 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 2015-20.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	UTTAM SARKAR,Assistant Section Officer	DGFT(HQ)
2	Raman Kumar,Deputy DGFT	DGFT(HQ)
3	NAND Lal,Technical Consultant	DPIIT
4	SHAISH KUMAR,Technical Consultant	DGFT
5	DINESHNARAIN MATHUR,Technical Consultant	DGFT
6	Nand Lal,Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Dec/202324/19
Case Status	Case Rejected
Party Name	CYKLO PHARMA CHEM PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00003200AM24
RA File Number	032404000318 AM04
Licence No and Date	0310204913/29/05/2003
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	2 / NC/3/MEET/Dec/202324/19
Case Status	Case Rejected
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00006970AM24
RA File Number	039404000337 AM12
Licence No and Date	0310646104/03/08/2011
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the there is no justification for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	3 / NC/3/MEET/Dec/202324/19				
Case Status	Case Approved				
Party Name	MOREPEN LABORATORIES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024				
HQ File Number	HQRNORM REVIW00006470AM23				
RA File Number	052404000420 AM14				
Licence No and Date	0510378413/05/02/2014				
Norms Committee Decision:					
Decision: The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.

(4R-CIS)-1, 1-DIMETHYLETHYL-6-[2-[2-(4-FLUOROPHENYL) -5-(1-ISOPROPYL)-3-PHENYL-4-[(PHENYLAMINO)(CARBONYL)-1H-PYRROLE-1-YL]ETHYL]-2,2-DIMETHYL-1,3-DIOXANE-4-ACETATE/ATORVASTAIN CALCIUM INTERMEDIATE)	2000 kg.	1	4-Fluoro-alpha-[2-methyl-1-oxopropyl]-gamma-oxo-N-beta-diphenyl benzene butanamide	No import made.
		2	(4R-Cis)-1,1-Dimethylethyl-6-cyanomethyl-2,2-dimethyl-1,3-dioxane -4-Acetate	903 kg.
		3	ISOPROPYL ALCOHOL	No import made
		4	CYCLOHEXANE	No import made
		5	METHANOL	No import made
		6	SODIUM BICARBONATE	No import made

Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms.

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

Case No.	4 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SATYAJIT CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005534AM24
RA File Number	NA
Licence No and Date	0310786462/07/07/2014
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	5 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ROYAL PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00006808AM24
RA File Number	039504000958 AM15
Licence No and Date	0310793866/12/02/2015

Norms Committee Decision:

Decision: Shri Padmakant Pandya, Manager (Exports), Shri Rutvij Purohit, Asstt. Manager (Exports) and Shri P.J. Gandhi, Technical Consultant of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BICALUTAMIDE SULFIDE CHEMICAL NAME: N-[4-CYANO-3-(TRIFLUORO METHYL)PHENYL]-3-[(4-FLUOROPHENYL THIO)] -2-HYDROXY-2-METHYL PROPIONALIDE	1 kg.	1	N-[4-CYANO-3- (TRIFLUORO METHYL)PHENYL] METHACRYLAMIDE MATERIAL FORMULA C12H9ON2F3 AND MATERIAL WEIGHT 254	0.750 kg.
		2	4-FLUOROTHIOPHENOL MATERIAL FORMULA C6H5F5 AND MATERIAL WEIGHT 128	0.344 kg.

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

Case No.	6 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	MOREPEN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00006437AM23
RA File Number	052404000073 AM16
Licence No and Date	0510394342/25/05/2015

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SITAGLIPTIN PHOSPHATE MONOHYDRATE	1 kg.	1	2,4,5-TRIFLUOROPHENYL ACETIC ACID	0.667 kg.
		2	1,3-DIOXANE-4,6-DIONE-2,2-DIMETHYL / 2,2-DIMETHYL-1,3-DIOXANE-4,6-DIONE	0.667 kg.

		3	3-(TRIFLUOROMETHYL)-5,6,7,8-TETRAHYDRO-[1,2,4] TRIAZOLO[4,3-A]PYRAZINE HYDROCHLORIDE	0.80 kg.
		4	D-(-) MANDELIC ACID / R-(-) MANDELIC ACID	0.667 kg.

Above norms based on Actual Import or by comparison is for closure and regularization purpose only.

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

Case No.	7 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00006509AM24
RA File Number	039504000267 AM18
Licence No and Date	0310814547/11/07/2017

Norms Committee Decision:

Decision : Shri Kunal Sikchi, Director and Shri Nitin Vyas, Sr. Executive of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less:-

Export Product	Qty	S.No.	Import Item	Qty. allowed
D Alpha Tocopherol having Net content of Fatty Acid Distillate/Deoderised Distillate 727000.00 kgs. Methenol 99 Percent 222400.00 kg. S Heptane 71200.00 kg. Acetone 29000.00 kg.	1 Kg.	1	Fatty Acid Distillate Deoderised Distillate	30.00 kg
		2	Methenol 99%	9.18 kg
		3	S-Heptane	2.94 kg
		4	Acetone	1.20 kg

Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms.

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

Case No.	8 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ROYAL PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00006805AM24
RA File Number	039504000424 AM18
Licence No and Date	0310815337/23/08/2017

Norms Committee Decision:

Decision: Shri Padmakant Pandya, Manager (Exports), Shri Rutvij Purohit, Asstt. Manager (Exports) and Shri P.J. Gandhi, Technical Consultant of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BICALUTAMIDE SULFIDE CHEMICAL NAME: N-[4-CYANO-3-(TRIFLUORO METHYL)PHENYL]-3-[(4-FLUOROPHENYL THIO)] -2-HYDROXY-2-METHYL PROPIONALIDE	1 kg.	1	N-[4-CYANO-3- (TRIFLUORO METHYL)PHENYL] METHACRYLAMIDE MATERIAL FORMULA C12H9ON2F3 AND MATERIAL WEIGHT 254	0.750 kg.
		2	4-FLUOROTHIOPHENOL MATERIAL FORMULA C6H5F5 AND MATERIAL WEIGHT 128	0.344 kg.

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

Case No.	9 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00002756AM23
RA File Number	522404000085 AM18
Licence No and Date	5210042570/20/03/2018

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/202223/4 dated 17/06/2022** against advance

authorization **No.5210042570 dated 20/03/2018**, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TERT- BUTYL 1-PIPERAZINE CARBOXYLATE (1-BOC PIPERAZINE)	1 kg.	1	DI- Tert Butyl Dicarbonate	2.00 kg.
		2	PIPERAZINE ANHYDROUS	0.80 kg.

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

Case No.	10 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SHREE BANKEY BEHARI LAL FLAVORS
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00006890AM24
RA File Number	052404000067 AM19
Licence No and Date	0510406412/10/05/2018
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Production/Consumption data for the year 2018-19 certified by GST.	

Case No.	11 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00001184AM23
RA File Number	092404000181 AM19
Licence No and Date	0910066442/11/07/2018
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.12/82-ALC4/2019 dated 17/01/2020 against advance authorization No. 0910065450 dated 11/09/2017 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Amoxycillin & Clavulanate Potassium OS 200/28.5mg per 5ml -50ml((The relevant Bulk Drug content in the Export Product is: Amoxycillin Trihydrate 100.00 Kgs + Syloid 14.25 KgA))	1000 Bottles	1	6-APA	1192.80 gm.
		2	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	707.00 gm.
Amoxycillin & Clavulanate Potassium OS 200/28.5mg per 5ml-75ml((The relevant Bulk Drug content in the Export Product is: Amoxycillin Trihydrate 90.00Kgs + Syloid 12.825 KgA))	1000 Bottles	3	6-APA	1789.2 gm.
		4	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	1060.50 gm.
Amoxycillin & Clavulanate Potassium OS 200/28.5mg per 5 ml-100ml((The relevant Bulk Drug content in the Export Product is: Amoxycillin Trihydrate 176.00 Kgs + Syloid 25.080 KgA))	1000 Bottles	5	6-APA	2385.6 gm.
		6	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	1414.00 gm.
Amoxycillin & Clavulanate Potassium OS 400/57mg per 5ml-50ml((The relevant Bulk Drug content in the Export Product is : Amoxycillin Trihydrate 240.00Kgs + Syloid 34.20 KgA))	1000 Bottles	7	6-APA	2385.60 gm.
		8	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	1414.0 gm.
Amoxycillin & Clavulanate Potassium OS 400/57mg per 5ml-75ml((The relevant Bulk Drug content in the Export Product is: Amoxycillin Trihydrate 720.00 Kgs + Syloid 102.60 KgA))	1000 Bottles	9	6-APA	3578.40 gm.
		10	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	2121.00 gm.
Amoxycillin & Clavulanate Potassium OS 400/57mg per 5ml-100ml((The relevant Bulk Drug content in the Export Product is: Amoxycillin Trihydrate 1760.00Kgs + Syloid 250.80 KgA))	1000 Bottles	11	6-APA	4771.20 gm.
		12	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	2828.00 gm.
Amoxycillin & Clavulanate Potassium Os 600/42.9mg per 5ml-75ml((The relevant Bulk Drug content in the Export Product is: Amoxycillin Trihydrate 1890.00Kgs + Syloid 135.135 KgA))	1000 Bottles	13	6-APA	5367.60 gm.
		14	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	1596.54 gm.

Amoxycillin & Clavulanate Potassium OS 600/42.9mg per 5ml-125ml((The relevant Bulk Drug content in the Export Product is: Amoxycillin Trihydrate 1650.00Kgs + Syloid 117.975 KgA))	1000 Bottles	15	6-APA	8946.00 gm.
		16	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	2660.91 gm.
Amoxycillin & Clavulanate Potassium OS 600/42.9mg per 5ml-200ml((The relevant Bulk Drug content in the Export Product is: Amoxycillin Trihydrate 1200.00Kgs + Syloid 85.80 KgA))	1000 Bottles	17	6-APA	14313.6 gm.
		18	Clavulanate Potassium + Syloid / Clavulanate Potassium Diluted with Silicon Dioxide (1:1)	4257.46 gm.

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

Case No.	12 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ROYAL PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00006804AM24
RA File Number	039504000720 AM19
Licence No and Date	0310824487/17/10/2018

Norms Committee Decision:

Shri Padmakant Pandya, Manager (Exports), Shri Rutvij Purohit, Asstt. Manager (Exports) and Shri P.J. Gandhi, Technical Consultant of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BICALUTAMIDE SULFIDE CHEMICAL NAME: N-[4-CYANO-3-(TRIFLUORO METHYL)PHENYL]-3- [(4-FLUOROPHENYL THIO)] -2-HYDROXY-2-METHYL PROPIONALIDE	1 kg.	1	N-[4-CYANO-3-(TRIFLUORO METHYL)PHENYL] METHACRYLAMIDE MATERIAL FORMULA C12H9ON2F3 AND MATERIAL WEIGHT 254	0.750 kg.
		2	4-FLUOROTHIOPHENOL MATERIAL FORMULA C6H5F5 AND MATERIAL WEIGHT 128	0.344 kg.

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

Case No.	13 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	VINS BIOPRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007011AM24
RA File Number	092404000363 AM19
Licence No and Date	0910066851/14/11/2018
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	14 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007177AM24
RA File Number	039504000889 AM19
Licence No and Date	0310825587/11/12/2018
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
Copy of Master Batch Formula still not given for each export items.	

Case No.	15 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ROYAL PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00006812AM24
RA File Number	039504000945 AM19
Licence No and Date	0310825646/13/12/2018
Norms Committee Decision:	
Decision: Shri Padmakant Pandya, Manager (Exports), Shri Rutvij Purohit, Asstt. Manager (Exports) and Shri P.J.	

Gandhi, Technical Consultant of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BICALUTAMIDE SULFIDE CHEMICAL NAME: N-[4-CYANO-3-(TRIFLUORO METHYL)PHENYL]-3-[(4-FLUOROPHENYL THIO)]-2-HYDROXY-2-METHYL PROPIONALIDE	1 kg.	1	N-[4-CYANO-3-(TRIFLUORO METHYL)PHENYL] METHACRYLAMIDE MATERIAL FORMULA C ₁₂ H ₉ ON ₂ F ₃ AND MATERIAL WEIGHT 254	0.750 kg.
		2	4-FLUOROTHIOPHENOL MATERIAL FORMULA C ₆ H ₅ F ₅ AND MATERIAL WEIGHT 128	0.344 kg.

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

Case No.	16 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00000817AM24
RA File Number	082404000026 AM20
Licence No and Date	0810145127/30/04/2019

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.0810145127 dated 30/04/2019**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
N-(3-AMINOPROPYL) IMIDAZOLE WHITE OR OFF WHITE CRYSTAL	1 kg.	1	Imidazole	0.712 kg.
		2	SODIUM METHOXIDE POWDER	1.00 kg.
		3	ACRYLONITRILE	0.500 kg.

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

Case No.	17 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007489AM24
RA File Number	092404000172 AM20
Licence No and Date	0910067749/03/07/2019

Norms Committee Decision:

Dr. Suresh Reddy Childipudi, R&D Head, and Shri T. Ram Prasad of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed
(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride of Aminoalcohol	1 kg.	1	KRED LYOPHILIZED ENZYME POWDER	0.0118 kg.

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

Case No.	18 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007504AM24
RA File Number	092404000275 AM20
Licence No and Date	0910067938/27/08/2019

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. 0911000023 dated 15/12/2020** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sodium(S)-4-oxo-4,6,7,8-tetrahydropyrrolo[1,2-a]pyrimidine-6-carboxylate	1 kg.	1	NORBORNADIENE TECH	2.00 kg.

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

Case No.	19 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00004718AM24
RA File Number	052404000296 AM20
Licence No and Date	0510411778/06/09/2019

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TESA-1-(3-CHLOROPYRIDIN-2YL)-3-[5-(TRIFLUOROMETHYL)-2H TETRAZOL-2YLMETHYL-1H- PYRAZOLE -5-CARBOXYLIC ACID	1 kg.	1	HYPE	0.905 kg.
		2	TFMT-NA (28% solution in Acetone)	1.91 kg.

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

Case No.	20 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	VINS BIOPRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00006988AM24
RA File Number	092404000410 AM20

Licence No and Date	0910068189/15/11/2019
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Batch Manufacturing record and material reconciliation sheet duly signed by dealing executive/manager from the applicant.	

Case No.	21 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00004716AM24
RA File Number	052404000445 AM20
Licence No and Date	0510412564/21/11/2019
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	22 / NC/3/MEET/Dec/202324/19				
Case Status	Case Approved				
Party Name	RUBICON RESEARCH PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024				
HQ File Number	HQRNORM REVIW00007128AM24				
RA File Number	039504000793 AM20				
Licence No and Date	0310833193/04/12/2019				
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. 3/82-ALC4/2020 dated 07.08.2020 against advance authorization No. 0310830404 dated 18.07.2019 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Cyclobenzaprine Tablet 5MG	1 Number	1	Anhydrous Lactose USP - NF (Super Tab 21 AN)	95.00 mg / 5 mg tablet
2	Cyclobenzaprine Tablet10 MG	1 Number	1	Anhydrous Lactose USP - NF (Super Tab 21 AN)	90.00 mg / 10 mg tablet

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

Case No.	23 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007129AM24
RA File Number	039504001166 AM20
Licence No and Date	0310835813/24/04/2020

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. 3/82-ALC4/2020 dated 07.08.2020** against advance authorization No. **0310830404 dated 18.07.2019**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Cyclobenzaprine Tablet 5MG	1 Number	1	Supertab 21 AN Anhydrous Lactose Ph .Eur Anhydrous lactose USP-NF,JP	95.00 mg / 5 mg tablet
2	Cyclobenzaprine Tablet 7.5 mg	1 Number	1	Supertab 21 AN Anhydrous Lactose Ph .Eur Anhydrous lactose USP-NF,JP	92.5 mg / 7.5 mg tablet
3	Cyclobenzaprine Tablet 10 MG	1 Number	1	Supertab 21 AN Anhydrous Lactose Ph .Eur Anhydrous lactose USP-NF,JP	90.00 mg / 10 mg tablet

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

Case No.	24 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024

and Date	
HQ File Number	HQRNORM REVIW00007125AM24
RA File Number	039504000025 AM21
Licence No and Date	0310835832/25/04/2020
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Drug Manufacturing Licence (DML) for each export item. 2. Master Batch Formula for each item.	

Case No.	25 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007123AM24
RA File Number	039504000062 AM21
Licence No and Date	0310836183/13/05/2020
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Get the license amended to show content of API in each export.	

Case No.	26 / NC/3/MEET/Dec/202324/19				
Case Status	Case Approved				
Party Name	SRF LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024				
HQ File Number	HQRNORM REVIW00004717AM24				
RA File Number	052404000258 AM21				
Licence No and Date	0510415088/02/09/2020				
Norms Committee Decision:					
The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.

TESA -1-(3-CHLOROPYRIDIN-2YL)-3-[5-(TRIFLUOROMETHYL)-2H TETRAZOL-2YLMETHYL-1H-PYRAZOLE-5-CARBOXYLIC ACID	1 kg.	1	HYPE	0.905 kg.
		2	TFMT-Na (28% solutions in Acetone)	1.91 kg.

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

Case No.	27 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ROYAL PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00006811AM24
RA File Number	039504000439 AM21
Licence No and Date	0310838908/15/10/2020

Norms Committee Decision:

Shri Padmakant Pandya, Manager (Exports), Shri Rutvij Purohit, Asstt. Manager (Exports) and Shri P.J. Gandhi, Technical Consultant of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BICALUTAMIDE SULFIDE CHEMICAL NAME: N-[4-CYANO-3-(TRIFLUORO METHYL)PHENYL]-3-[(4-FLUOROPHENYL THIO)] -2-HYDROXY-2-METHYL PROPIONALIDE	1 kg.	1	N-[4-CYANO-3- (TRIFLUORO METHYL)PHENYL] METHACRYLAMIDE MATERIAL FORMULA C12H9ON2F3 AND MATERIAL WEIGHT 254	0.750 kg.
		2	4-FLUOROTHIOPHENOL MATERIAL FORMULA C6H5F5 AND MATERIAL WEIGHT 128	0.344 kg.

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

Case No.	28 / NC/3/MEET/Dec/202324/19
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Case Status	Case Approved			
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM APPLY 00005163AM24			
RA File Number	NA			
Licence No and Date	0310839717/25/11/2020			
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/202223/3 dated 27.05.2022 against advance authorization No. 0311005861 dated 04.08.2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export product	Qty.	Sl. No.	Import items	Qty.
Carbamazepine Extended Release Tablets USP 100mg,(Each Tablet Contains (1) Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)-35.04mg, 2) Cellulose Acetate (CA -320S)-Eastman 5.28mg. Net content (i) 3650.010 (ii) 550.000)	1 Number	1	Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)	4.40 mg
		2	Cellulose Acetate (CA-320S Eastman)	29.20 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	29 / NC/3/MEET/Dec/202324/19			
Case Status	Case Approved			
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM REVIW00004711AM24			
RA File Number	039404000659 AM21			
Licence No and Date	0310839748/26/11/2020			
Norms Committee Decision:				
The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DIISOPROPYL ETHER	1 kg.	1	DIISOPROPYL ETHER	1.25 kg.

(Purity more than 99.21%) (Moisture less than 1000 PPM)			(Purity not more than 95%)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	30 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	MAC-CHEM PRODUCTS (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00005491AM24
RA File Number	NA
Licence No and Date	0311000185/17/12/2020
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. Complete Chemistry, Molecular weight, Percentage Yield and Material Balance for Lyophilised sterile Bulk.	

Case No.	31 / NC/3/MEET/Dec/202324/19			
Case Status	Case Approved			
Party Name	OPTIMUS DRUGS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM REVIW00006917AM24			
RA File Number	09AA04002675 AM21			
Licence No and Date	0911000050/18/12/2020			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Pyrimidinone acid, sodium salt sodium((S)-4-oxo-4,6,7,8-tetrahydropyrrolo [1,2-a]pyrimidine-6-carboxylate)	1 kg.	1	Methyl L-pyroglyutamate	2.70 kg.
		2	Triethyl amine	2.27 kg.

		3	2,5 Norbornadiene	2.00 kg.
		4	Chloro sulfonyl isocyanate	2.778 kg.
		5	Isopropyl alcohol	4.02 kg.

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

Case No.	32 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007127AM24
RA File Number	039504000557 AM21
Licence No and Date	0311000313/22/12/2020

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. 3/82-ALC4/2020 dated 07.08.2020** against advance authorization No. **0310830404 dated 18.07.2019**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Cyclobenzaprine Tablet 5MG	1 Number	1	Supertab 21 AN Anhydrous Lactose Ph .Eur Anhydrous lactose USP-NF,JP	95.00 mg / 5 mg tablet
2	Cyclobenzaprine Tablet 7.5 mg	1 Number	1	Supertab 21 AN Anhydrous Lactose Ph .Eur Anhydrous lactose USP-NF,JP	92.5 mg / 7.5 mg tablet
3	Cyclobenzaprine Tablet10 MG	1 Number	1	Supertab 21 AN Anhydrous Lactose Ph .Eur Anhydrous lactose USP-NF,JP	90.00 mg / 10 mg tablet

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

Case No.	33 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SV PLASTOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007423AM24
RA File Number	31AA04007148 AM21
Licence No and Date	3111000400/14/06/2021

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.14/82-ALC4/2019 dated 06/03/2020** against advance authorization **No.3110067406 dated 02/05/2019**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRI BUTYL TIN OXIDE (TBTO)	1 kg.	1	TIN INGOTS	0.122 kg.
		2	TETRA BUTYL TIN TBT	0.969 kg.

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

Case No.	34 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	VARTIKA CHEMICALS AND PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00002099AM23
RA File Number	NA
Licence No and Date	1311000462/22/07/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MEROPENEM STERILE IP (Sterile Powder for injection	1 kg.	1	Meropenem Trihydrate (Non-sterile)	0.8968 kg.

(Antibiotic))

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

Case No.	35 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00148419AM22
RA File Number	31AA04021097 AM22
Licence No and Date	3111000476/27/07/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Radicate Spot on 12 (For small dog) (6 Pipettes Pack)) 0.5 ml.	180.0 Number	1	Selamectin BP	66.096 gm.
Radicate Spot on 12 (For medium dog) (6 Pipettes Pack)) 1 ml.	150.0 Number	2	Selamectin BP	110.16 gm.
Radicate Spot on 12(Radicate Spot on 12 (For large dog) (6 Pipettes Pack)) 2 ml.	100.0 Number	3	Selamectin BP	146.88 gm.
Radicate Spot on 12(Radicate Spot on 12 (For Extra large dog) (6 Pipettes Pack)) 3 ml.	100.0 Number	4	Selamectin BP	220.32 gm.
Radicate Spot on 12(Radicate Spot on 12 (For Cat) (6 Pipettes Pack)) 0.75 ml.	2500.0 Number	5	Selamectin BP	708.75 gm.
Radicate Spot on 12(Radicate Spot on 12 (For small dog) (1 Pipettes Pack)) 0.5 ml.	2000.0 Number	6	Selamectin BP	122.40 gm.
Radicate Spot on 12(Radicate Spot on 12 (For medium dog) (1 Pipettes Pack)) 1 ml	2000.0 Number	7	Selamectin BP	244.80 gm.

Radicat Spot on 12(Radicat Spot on 12 (For large dog) (1 Pipettes Pack)) 2 ml.	1000.0 Number	8	Selamectin BP	244.80 gm.
Radicat Spot on 12(Radicat Spot on 12 (For Extra large dog) (1 Pipettes Pack)) 3 ml.	250.0 Number	9	Selamectin BP	91.80 gm.
Petmedin 1.25 mg Tablets(Petmedin 1.25 mg Tablets)	1 Number each	10	Selamectin BP	1.275 mg.
Petmedin 2.5 mg Tablets(Petmedin 2.5 mg Tablets)	1 Number each	11	Selamectin BP	2.55 mg.
Petmedin 5 mg Tablets(Petmedin 5 mg Tablets)	1 Number each	12	Selamectin BP	5.10 mg.
Petmedin 10 mg Tablets(Petmedin 10 mg Tablets)	1 Number each	13	Selamectin BP	10.20 mg.

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

Case No.	36 / NC/3/MEET/Dec/202324/19			
Case Status	Case Approved			
Party Name	RAJASTHAN ANTIBIOTICS LTD			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM APPLY 00150875AM22			
RA File Number	05AA04055660 AM22			
Licence No and Date	0511003910/30/07/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
KETOPROFEN BP (STERILE POWDER) (32.3 Percentage TO 39.5 Percentage W/W)	1 kg.	1	KETOPROFEN BP	0.363 kg.

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

Case No.	37 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00164102AM22
RA File Number	03AA04065031 AM22
Licence No and Date	0311006216/17/08/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	38 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00165403AM22
RA File Number	05AA04062260 AM22
Licence No and Date	0511004178/18/08/2021
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Complete Chemistry, Molecular Weight and Percentage Yield on molar basis for each export products.	

Case No.	39 / NC/3/MEET/Dec/202324/19			
Case Status	Case Approved			
Party Name	CHEMPLAST SANMAR LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM REVIW00006805AM23			
RA File Number	04AA04015436 AM22			
Licence No and Date	0411001511/22/09/2021			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Phenyl Guanidine Carbonate	1 kg.	1	Hydrogen Cyanamide 30 Percent	1.48 kg.

		2	Aniline	0.682 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	40 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	AMARA LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00211472AM22
RA File Number	09AA04016055 AM22
Licence No and Date	0911001711/13/10/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Deferiprone	1 kg.	1	Maltol	1.26 kg.

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

Case No.	41 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	LUPIN LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00005265AM24
RA File Number	03AA040109357 AM22
Licence No and Date	0311007760/18/10/2021

Norms Committee Decision:

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

1. Copy of Drug Manufacturing Licence (DML) for export items.
2. Complete chemistry, Molecular Weight, Percentage Yield on molar basis for API.

Case No.	42 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	BHAGWATI INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00219420AM22
RA File Number	08AA04033013 AM22
Licence No and Date	0811002934/21/10/2021
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Chemistry of the export item giving molecular weight of both reactant and the products. 2. Yield of the reaction with justification and to indicate by-product formed with value, if any.	

Case No.	43 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00239769AM22
RA File Number	09AA04001389 AM22
Licence No and Date	0911001808/02/11/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	44 / NC/3/MEET/Dec/202324/19								
Case Status	Case Approved								
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024								
HQ File Number	HQRNORM APPLY 00253270AM22								
RA File Number	05AA04099135 AM22								
Licence No and Date	0511006147/15/11/2021								
Norms Committee Decision:									
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-									
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.					

Tretinoin Microspheres,2%	1 kg.	1	Tretinoin USP	0.021 kg.
Placebo Tretinoin Microspheres,2%	1 kg.	2	Tretinoin USP	0.021 kg.

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

Case No.	45 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00255297AM22
RA File Number	34AA04009240 AM22
Licence No and Date	3411001409/17/11/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
FOAM (BETAMETHASONE VALERATE FOAM, 0.12% (50G CAN) (net content of active ingredient 600gm))	1 Number	1	BETAMETHASONE VALERATE (Micronized)	0.0612 gm.
FOAM (BETAMETHASONE VALERATE FOAM, 0.12% (100G CAN) (net content of active ingredient 900gm))	1 Number	2	BETAMETHASONE VALERATE (Micronized)	0.1224 gm.

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

Case No.	46 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	NATCO PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVW00004488AM24
RA File Number	09AX04000043 AM22
Licence No and Date	0911002121/21/12/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NITROGLYCERIN SUBLINGUAL TABLETS USP 0.3 mg Each Tablet contains Nitroglycerin USP 0.3 mg (2x1,80,000=3,60,000 Tablets)	1 Number	1	DILUTED NITROGLYCERIN USP 1.95 percent	16.105 mg
		2	Glyceryl Monosterate (Imwitor 491 powder)	1.255 mg
NITROGLYCERIN SUBLINGUAL TABLETS USP 0.4mg Each Tablet contains Nitroglycerin USP 0.4 mg (4x12,00,000=48,00,000 Tablets)	1 Number	3	DILUTED NITROGLYCERIN USP 1.95 percent	21.474 mg
		4	Glyceryl Monosterate (Imwitor 491 powder)	1.255 mg
NITROGLYCERIN SUBLINGUAL TABLETS USP 0.6 mg Each Tablet contains Nitroglycerin USP 0.6 mg (2x1,80,000=3,60,000 Tablets)	1 Number	5	DILUTED NITROGLYCERIN USP 1.95 percent	32.21 mg
		6	Glyceryl Monosterate (Imwitor 491 powder)	1.255 mg

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

Case No.	47 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SV PLASTOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007424AM24
RA File Number	31AX04000016 AM22
Licence No and Date	3111000805/21/12/2021

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/202223/20 dated 24/02/2023** against advance

authorization **No.3111000540 dated 23/08/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MONO BUTYL TIN OXIDE (MBTO)	1 kg.	1	TIN INGOTS	0.496 kg.
		2	TETRA BUTYL TIN TBT	0.487 kg.

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

Case No.	48 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00299344AM22
RA File Number	07AA04038998 AM22
Licence No and Date	0711002737/28/12/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	49 / NC/3/MEET/Dec/202324/19				
Case Status	Case Approved				
Party Name	RUBICON RESEARCH PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024				
HQ File Number	HQRNORM REVIW00007179AM24				
RA File Number	03AX04000191 AM22				
Licence No and Date	0311009972/31/12/2021				
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. 3/82-ALC4/2020 dated 07.08.2020 against advance authorization No. 0310830404 dated 18.07.2019 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.

1	Cyclobenzaprine Tablet 5MG	1 Number	1	Supertab 21 AN Anhydrous Lactose Ph .Eur Anhydrous lactose USP-NF,JP	95.00 mg / 5 mg tablet
2	Cyclobenzaprine Tablet 7.5 mg	1 Number	1	Supertab 21 AN Anhydrous Lactose Ph .Eur Anhydrous lactose USP-NF,JP	92.5 mg / 7.5 mg tablet
3	Cyclobenzaprine Tablet 10 MG	1 Number	1	Supertab 21 AN Anhydrous Lactose Ph .Eur Anhydrous lactose USP-NF,JP	90.00 mg / 10 mg tablet

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

Case No.	50 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00326841AM22
RA File Number	09AA04016329 AM22
Licence No and Date	0911002348/21/01/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Meropenem for Injection (Sterile Bulk) USP	1 kg.	1	Meropenem Trihydrate (Non-Sterile) I.P	0.8968 kg.
		2	Acetone	2.64 kg.
		3	Methanol (Methyl Alcohol)	0.80 kg.
		4	Aluminium Canister 14 Ltr.(5Kg) with Inner and Outer Lids	Relevant, as per Packing Policy

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

Case No.	51 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00345828AM22
RA File Number	09AX04000205 AM22
Licence No and Date	0911002465/07/02/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	52 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00346268AM22
RA File Number	34AX04000204 AM22
Licence No and Date	3411001767/07/02/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case alongwith relevant documents.	

Case No.	53 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00350237AM22
RA File Number	05AX04000943 AM22
Licence No and Date	0511008753/10/02/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	54 / NC/3/MEET/Dec/202324/19
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Case Status	Case Deferred
Party Name	GANGWAL HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00356909AM22
RA File Number	03AX04001205 AM22
Licence No and Date	0311011422/16/02/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	55 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00371441AM22
RA File Number	09AX04000232 AM22
Licence No and Date	0911002575/01/03/2022
Norms Committee Decision:	
The firm has informed that they have surrendered their above license. In view of the information from the firm, the Committee decided to withdraw the case.	

Case No.	56 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00386056AM22
RA File Number	08AX04000650 AM22
Licence No and Date	0811004377/14/03/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	57 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	PROEC ENERGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00005029AM24
RA File Number	05AX04001262 AM22

Licence No and Date	0511010975/14/03/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	58 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00000257AM24
RA File Number	03AX04001590 AM22
Licence No and Date	0311013222/22/03/2022

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/202122/13 dated 21/01/2022** against advance authorization **No.0311005784 dated 01/08/2021** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. allowed
1	Telmisartan and Amlodipine Tablets 40/10mg / Each uncoated tablets contains :(Telmisartan 40 mg Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is 2020.800 Kgs. Net wt of Amlodipine Besilate is 300.000 Kgs.)	1 Number	1	Telmisartan Granules	68.034 mg
			2	Amlodipine Besilate	10.20 mg
2	Telmisartan and Amlodipine Tablets 80/10mg / Each uncoated tablets contains : Telmisartan 80 mg(Telmisartan 80 mg equivalent to Telmisartan granules 134.72mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is 10777.600 Kgs. Net wt of Amlodipine Besilate is 800.000 Kgs.)	1 Number	3	Telmisartan Granules	136.07 mg
			4	Amlodipine Besilate	10.20 mg
3	Telmisartan and Amlodipine Tablets 40/5mg / Each uncoated tablets contains : Telmisartan 40 mg(Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 5mg Net wt of Telmisartan Granules is 6286.933 Kgs. Net wt of Amlodipine Besilate is 466.667 Kgs.)	1 Number	5	Telmisartan Granules	68.034 mg
			6	Amlodipine Besilate	5.10 mg

4	Telmisartan and Amlodipine Tablets 80/5mg / Each uncoated tablets contains : Telmisartan 80 mg(Telmisartan 80 mg equivalent to Telmisartan granules 134.72mg Amlodipine Besilate equivalent to Amlodipine USP 5mg Net wt of Telmisartan Granules is 10777.600 Kgs. Net wt of Amlodipine Besilate is 400.000 Kgs.)	1 Number	7	Telmisartan Granules	136.07 mg
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Case No.	59 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ARENE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00000197AM23
RA File Number	09AX04000016 AM23
Licence No and Date	0911002850/12/04/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	60 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00000485AM23
RA File Number	03AX04000399 AM23
Licence No and Date	0311014263/29/04/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	61 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00005291AM24
RA File Number	31AX04000028 AM23
Licence No and Date	3111001358/17/05/2022
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DNOVO BP818	1 kg.	1	OCP 50	1.100 kg.
		2	Paraformaldehyde	0.141 kg.
		3	Methanol	0.66 kg.
		4	Katalco 71 5	0.004 kg.

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

Case No.	62 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	NATCO PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00004490AM24
RA File Number	09AX04000174 AM23
Licence No and Date	0911003150/08/06/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NITROGLYCERIN SUBLINGUAL TABLETS USP 0.3 mg-Each Tablet contains Nitroglycerin USP 0.3 mg (1 x 1,80,000 = 1,80,000 Tabs)	1 Number	1	DILUTED NITROGLYCERIN USP 1.95 %	16.105 mg.
		2	Glyceryl Monostearate (Imwitor 491 powder)	1.60 mg.
NITROGLYCERIN SUBLINGUAL TABLETS USP 0.4 mg-Each Tablet	1 Number	3	DILUTED NITROGLYCERIN USP	21.474 mg.

contains Nitroglycerin USP 0.4 mg (3 x12,00,000= 36,00,000 Tabs)			1.95 %	
		4	Glyceryl Monostearate (Imwitor 491 powder)	1.60 mg.

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

Case No.	63 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	NASENSE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00001297AM23
RA File Number	09AX04000213 AM23
Licence No and Date	0911003160/09/06/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	64 / NC/3/MEET/Dec/202324/19			
Case Status	Case Approved			
Party Name	ROYAL PHARMA			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM REVIW00006658AM24			
RA File Number	03AX04001263 AM23			
Licence No and Date	0311015473/13/06/2022			
Norms Committee Decision:				
Shri Padmakant Pandya, Manager (Exports), Shri Rutvij Purohit, Asstt. Manager (Exports) and Shri P.J. Gandhi, Technical Consultant of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BICALUTAMIDE SULFIDE CHEMICAL NAME: N-[4-CYANO-3-(TRIFLUORO METHYL)PHENYL]-3-	1 kg.	1	N-[4-CYANO-3-(TRIFLUORO METHYL)PHENYL] METHACRYLAMIDE	0.750 kg.

[(4-FLUOROPHENYL THIO)] -2-HYDROXY-2-METHYL PROPIONALIDE			MATERIAL FORMULA C12H9ON2F3 AND MATERIAL WEIGHT 254	
		2	4-FLUOROTHIOPHENOL MATERIAL FORMULA C6H5F5 AND MATERIAL WEIGHT 128	0.344 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	65 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007068AM24
RA File Number	05AX04001017 AM23
Licence No and Date	0511013648/07/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	66 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007056AM24
RA File Number	05AX04001011 AM23
Licence No and Date	0511013749/13/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	67 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007416AM24
RA File Number	34AX04000357 AM23

Licence No and Date	3411002528/13/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	68 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007032AM24
RA File Number	05AX04001131 AM23
Licence No and Date	0511013929/22/07/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2,2-difluoro-1,3-benzodioxole(DFBD)	1 kg.	1	2.2 AZOBISISOBUTYRONITRILE(AIBN)	0.0176 kg
		2	BENZOTRIFLUORIDE (BTF)	0.0684 kg.
		3	1,3-BENZODIOXOLE	0.898 kg.

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

Case No.	69 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004780AM24
RA File Number	NA
Licence No and Date	0311016601/26/07/2022

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/202324/16 dated 17/11/2023** against advance authorization No. **0311009090 No. dated 02/12/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DIISOPROPYL ETHER (Purity more than 99.21%) (Moisture less than 1000 PPM)	1 kg.	1	CRUDE DIISOPROPYL ETHER (Purity not more than 95%)	1.25 kg.

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

Case No.	70 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00005227AM24
RA File Number	31AX04000141 AM23
Licence No and Date	3111001623/17/08/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DNOVO BP818 (Tetra Methyl Bisphenol F)	1 kg.	1	OCP 50	1.100 kg.
		2	Paraformaldehyde	0.141 kg.
		3	Methanol	0.66 kg.
		4	Katalco 71 5	0.004 kg.

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

Case No.	71 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SHREE MAHADEV INTERMEDIATE
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00005358AM24
RA File Number	34AX04000640 AM23
Licence No and Date	3411002862/04/10/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- “Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.”	

Case No.	72 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00005140AM24
RA File Number	08AX04001050 AM23
Licence No and Date	0811006214/10/10/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	73 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007058AM24
RA File Number	05AX04002096 AM23
Licence No and Date	0511015534/31/10/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	74 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	MAXTAR BIO GENICS

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004225AM23
RA File Number	05AX04002243 AM23
Licence No and Date	0511015686/09/11/2022
Norms Committee Decision:	
The committee considered the request of the firm for fixation of ad-hoc norms and it was decided that the firm may be advised to get their Advance Authorization amended for complete description of export product as per their DML	

Case No.	75 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004250AM23
RA File Number	05AX04002186 AM23
Licence No and Date	0511015716/09/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	76 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004256AM23
RA File Number	03AX04004034 AM23
Licence No and Date	0311019116/10/11/2022
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms for export to US only are as under:-	

(ii)	Medical Creams & Ointments(SECURA EXTRA PROTECTIVE CREAM 7.75 Oz 219.70 GM Tot wt: 7792.10Kgs (Net Cont: White Pet 3180.74Kgs, Ceto 476.88Kgs, Methyl 397.40Kgs, Akucell 238.44 Kgs, Karaya 556.36kgs,Diaz 15.58 Kgs))	1 Number
(iii)	Medical Creams & Ointments(SECURA ANTIFUNGAL EXTRA THICK PROTECTIVE CREAM 3.25 Oz 92 GM Tot wt: 5883.40 Kgs (Net Cont: White Pet 2353.36Kgs, Ceto 353Kgs, Methyl 294.17Kgs, Akucell 176.50 Kgs, Karaya 411.84kgs,Diaz 11.77Kgs))	1 Number
(iv)	Medical Creams & Ointments(SECURA EXTRA PROTECTIVE CREAM 90 GMS TUBE Tot wt: 1918.17Kgs (Net Cont: White Pet 783Kgs, Ceto 117.39Kgs, Methyl 97.83Kgs, Akucell 58.70 Kgs, Karaya 136.96kgs,Diaz 3.84 Kgs))	1 Number

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

Note:

- 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**
- 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**
- The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	77 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004258AM23
RA File Number	03AX04003990 AM23
Licence No and Date	0311019120/10/11/2022
Norms Committee Decision:	

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

Case No.	78 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	BOTANIC HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004273AM23
RA File Number	09AX04000641 AM23
Licence No and Date	0911003939/10/11/2022

Norms Committee Decision:

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

- 1. Manufacturing process indicating stage wise wastage of raw materials.**
- 2. Chemistry of the reaction giving molecular weight of reactant and product.**
- 3. CoA report (indicating composition) of both import and export items and to give calculation for the requirement of raw materials both imported and indigenously indicating.**

Case No.	79 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004284AM23
RA File Number	04AX04000700 AM23
Licence No and Date	0411004428/11/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202324/8 dated 30.06.2023** against advance authorization **No. 0411005200 dated 06/04/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
IBUPROFEN	1 Kg.	1	ISOBUTYL ACETOPHENONE	1.110 kg.
		2	SODIUM METAL	0.235 kg.

		3	MONOCHLORO ACETIC ACID	0.919 kg.
		4	ISO PROPYL ALCOHOL	0.500 kg.
		5	SODIUM DICHROMATE	0.630 kg.

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

Case No.	80 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004335AM23
RA File Number	09AA04002473 AM22
Licence No and Date	0911003950/14/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202122/2 dated 02/07/2021** against advance authorization **No. 0911000974 dated 31/05/2021**, 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.
(1R,2S,5R)-2-Isopropyl-5-methylcyclohexyl-(2R,5S)-5-(4-amino-2-oxopyrimidin-1-(2H)-yl)-1,3-oxathiolane-2-carboxylate.((1R,2S,5R)-2-Isopropyl-5-methylcyclohexyl-(2R,5S)-5-(4-amino-2-oxopyrimidin-1-(2H)-yl)-1,3- oxathiolane-2-carboxylate. (OR) Cyclohexyl Ester (PE) (OR) Cyclohexyl Ester HN)	200000 kg	1	N,N-Dimethyl formamide	56,000 kg
		2	Hexamethyl disilazane	1,41,600 kg
		3	Cytosine	86,800 kg
		4	Triphosgene	1,00,000 kg

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

Case No.	81 / NC/3/MEET/Dec/202324/19																
Case Status	Case Approved																
Party Name	SRF LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024																
HQ File Number	HQRNORM APPLY 00004336AM23																
RA File Number	05AX04002273 AM23																
Licence No and Date	0511015796/14/11/2022																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="3">2,2-difluoro-1,3-benzodioxole(DFBD)</td><td rowspan="3">1 kg.</td><td>1</td><td>2.2 AZOBISISOBUTYRONITRILE(AIBN)</td><td>0.0176 kg.</td></tr><tr><td>2</td><td>BENZOTRIFLUORIDE (BTF)</td><td>0.0684 kg.</td></tr><tr><td>3</td><td>1,3-BENZODIOXOLE</td><td>0.898 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	2,2-difluoro-1,3-benzodioxole(DFBD)	1 kg.	1	2.2 AZOBISISOBUTYRONITRILE(AIBN)	0.0176 kg.	2	BENZOTRIFLUORIDE (BTF)	0.0684 kg.	3	1,3-BENZODIOXOLE	0.898 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
2,2-difluoro-1,3-benzodioxole(DFBD)	1 kg.	1	2.2 AZOBISISOBUTYRONITRILE(AIBN)	0.0176 kg.													
		2	BENZOTRIFLUORIDE (BTF)	0.0684 kg.													
		3	1,3-BENZODIOXOLE	0.898 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	82 / NC/3/MEET/Dec/202324/19													
Case Status	Case Approved													
Party Name	INTAS PHARMACEUTICALS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024													
HQ File Number	HQRNORM APPLY 00004383AM23													
RA File Number	08AX04001342 AM23													
Licence No and Date	0811006452/16/11/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No. 0811004640 dated 13/04/2022 , 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>METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS:</td><td>1 Number Vial</td><td>1</td><td>METHOTREXATE</td><td>61.87 mg/vial</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS:	1 Number Vial	1	METHOTREXATE	61.87 mg/vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS:	1 Number Vial	1	METHOTREXATE	61.87 mg/vial										

METHOTREXATE PH. EUR. 25MG)			EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	
METHOTREXATE INJECTION BP 100MG/ML [5 ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100 MG)	1 Number Vial	2	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	618.70 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL](EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)	1 Number Vial	3	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	1237.39 mg/vial
METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL](EACH ML CONTAINS: METHOTREXATE USP 25MG)	1 Number Vial	4	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	306.867 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [20ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	5	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	590.57 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	6	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	1181.15 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 8.175 KGS.])	1 Number Vial	7	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49 % in API)	5737.00 mg/vial

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

Case No.	83 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004409AM23
RA File Number	03AX04003954 AM23
Licence No and Date	0311019281/17/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	84 / NC/3/MEET/Dec/202324/19			
Case Status	Case Approved			
Party Name	GRANULES INDIA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM APPLY 00004411AM23			
RA File Number	09AX04000695 AM23			
Licence No and Date	0911003896/17/11/2022			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Methocarbamol	1 Kg.	1	Guaifenesin	1.05 kg.
		2	Sodium Methoxide Powder	0.005 kg.
		3	Dimethyl Carbonate	0.500 kg.
		4	Ammonium Chloride	0.015 kg.
		5	Ammonia Gas	0.250 kg.

		6	Toluene	0.300 kg.
		7	Methanol	0.700 kg.
		8	Activated carbon	0.005 kg.

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

Case No.	85 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ENVEE DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004428AM23
RA File Number	34AX04000741 AM23
Licence No and Date	3411003006/17/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	86 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004437AM23
RA File Number	03AX04003955 AM23
Licence No and Date	0311019320/18/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	87 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004468AM23
RA File Number	34AX04000711 AM23
Licence No and	3411003022/18/11/2022

Date

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/Jul/202324/9 dated 28/07/2023** against advance authorization **No. 3411000924 dated 02/08/2021** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Hexyl Salicylate (n-Hexyl-ortho-Hydroxy Benzoate)	1 kg.	1	n-Hexanol (Lorol C 6/ Nacol 6)	0.510 kg.
		2	Salicylic Acid	0.682 kg.

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

Case No.	88 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004509AM23
RA File Number	09AX04000587 AM23
Licence No and Date	0911003994/21/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	89 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004510AM23
RA File Number	04AX04000675 AM23
Licence No and Date	0411004400/21/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Apr/202324/1 dated 28/04/2023 against advance authorization No. 0411004581 dated 07/12/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details	

given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
IBUPROFEN	1 kg.	1	Isobutyl Acetophenone	1.11 kg.
		2	Sodium Metal	0.235 kg.
		3	Monochloro Acetic Acid	0.919 kg.
		4	Isopropyl Alcohol	0.50 kg.
		5	Sodium Dichromate	0.630 kg.

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

Case No.	90 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004512AM23
RA File Number	09AX04000684 AM23
Licence No and Date	0911003996/21/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments from Deptt. of Bio-Technology.	

Case No.	91 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004522AM23
RA File Number	08AX04001395 AM23
Licence No and Date	0811006510/22/11/2022

Norms Committee Decision:

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

Case No.	92 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004528AM23
RA File Number	03AX04003867 AM23
Licence No and Date	0311019424/22/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call the firm for attending **Personal Hearing** before Norms Committee to explain its case alongwith relevant documents.

Case No.	93 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004554AM23
RA File Number	05AX04002424 AM23
Licence No and Date	0511015979/23/11/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TELMISARTAN USP/EP(POWDER)	1 kg.	1	2-n-propyl-4-methyl-6-(1-methylbenzimidazol-2-yl)	0.621 kg.
		2	2-Cyano-4-Methyl Biphenyl (OTBN)	0.650 kg.
		3	Acetic acid	0.90 kg.
		4	Toluene	1.71 kg.

		5	Methylene Chloride	1.34 kg.
		6	Methanol	1.25 kg.

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

Case No.	94 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004555AM23
RA File Number	09AX04000691 AM23
Licence No and Date	0911004009/23/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	95 / NC/3/MEET/Dec/202324/19			
Case Status	Case Approved			
Party Name	GLENMARK LIFE SCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM APPLY 00004563AM23			
RA File Number	03AX04004200 AM23			
Licence No and Date	0311019475/24/11/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No.0311013777 dated 11/04/2022 , 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.
ROSUVASTATIN CALCIUM	1 kg.	1	Tert-Butyl(E)-(6-(2-(4-(4-fluorophenyl)-6-Isopropyl-2-(Methyl(Methyl Sulfonyl) Amino Pyrimidin-5-yl)Vinyl)(4R,6S)-2,2-Dim	1.30 kg.

		2	ETHYL ACETATE	0.674 kg.
		3	METHANOL	1.874 kg.
		4	TOLUENE	0.772 kg.
		5	ACETONITRILE	1.00 kg.

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

Case No.	96 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004575AM23
RA File Number	31AX04000236 AM23
Licence No and Date	3111001838/24/11/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Drug Manufacturing Licence (DML) for each export item. 2. Master Batch Formula for each item.	

Case No.	97 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	NICHINO INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004577AM23
RA File Number	09AX04000753 AM23
Licence No and Date	0911004012/24/11/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	98 / NC/3/MEET/Dec/202324/19
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Case Status	Case Deferred
Party Name	VIRCHOW DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004590AM23
RA File Number	09AX04000666 AM23
Licence No and Date	0911004017/24/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	99 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004603AM23
RA File Number	03AX04004186 AM23
Licence No and Date	0311019528/25/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202223/15 dated 29/12/2022** against advance authorization No. **0311015328 dated 07/06/2022**, 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.
Maxigesic cold & flu Hot Drink 500mg/150mg Sachets (Paracetamol & Ibuprofen Sachets 500 mg & 150 mg)(Maxigesic cold & flu Hot Drink 500mg/150mg Sachets (Paracetamol & Ibuprofen Sachets 500 mg & 150 mg) (Net content of Ibuprofen Lysine Salt IH API 359.10 kg))	1 NUMBER	1	Ibuprofen Lysine Salt IH	258.88 mg / Sachet
Maxigesic cold & flu Hot Drink 1000mg/300mg Sachets (Paracetamol & Ibuprofen Sachets 1000 mg & 300 mg)(Maxigesic cold & flu Hot Drink 1000mg/300mg Sachets (Paracetamol & Ibuprofen Sachets 1000 mg & 300 mg) (Net content of Ibuprofen Lysine Salt IH	1 NUMBER	2	Ibuprofen Lysine Salt IH	517.77 mg / Sachet

API 718.20 kg))				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	100 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	NICHINO INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004625AM23
RA File Number	09AX04000754 AM23
Licence No and Date	0911004025/28/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	101 / NC/3/MEET/Dec/202324/19			
Case Status	Case Approved			
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM APPLY 00004626AM23			
RA File Number	03AX04004277 AM23			
Licence No and Date	0311019549/28/11/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Oct/202324/15 dated 13/10/2023 against advance authorization No. 0311004745 dated 19/06/2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE) [Containing NLT 84% Sterile Meropenem]	1 kg.	1	MEROPENEM NON STERILE MEROPENEM TRIHYDRATE NON STERILE	0.8968 kg.
		2	Packing Material	Relevant, as per Packing Policy

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

Case No.	102 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004628AM23
RA File Number	03AX04004211 AM23
Licence No and Date	0311019551/28/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization No. **0311023306 dated 03/05/2023**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export Product	Qty.	Sl. No.	Import Items	Qty.
OLMESARTAN MEDOXOMIL	1 Kg.	1	4-(1-HYDROXY-1-METHYL ETHYL)-2-PROPYL-1H-IMIDAZOLE 5-CARBOXYLIC ACID ETHYL ESTER	0.70 kg.
		2	5-(4-BROMOMETHYL) (1 BROMOMETHYLIPHENYL) 2YL TRIPHENYL 1 H TETRAZOLE 5 (4 BROMOMETHYL BIPHENYL 2 YL) 1 TRITYL-1H TET	1.35 kg.
		3	4-CHLOROMETHYL-5-METHYL 1,3-DIOXOLEN-2-ONE	0.426 kg.
		4	ACETIC ACID GLACIAL	0.60 kg.
		5	ACETONE	3.00 kg.
		6	METHANOL	2.60 kg.
		7	TOLUENE	1.00 kg.

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

Case No.	103 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004629AM23
RA File Number	03AX04004039 AM23
Licence No and Date	0311019553/28/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jun/202223/5 dated 08.07.2022** against advance authorization No. **0311004856 dt. 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.
Potassium Chloride Extended Release Capsules 600mg / Potassium Chlor ER Caps USP 600mg MICRO-K Extencaps 600mg((Pack Size 100 Capsules Each) Each extended Release Capsule contains: Potassium Chloride USP 600mg)	1 Number of capsule	1	POTASSIUM CHLORIDE USP	612.0 mg
		2	CITRIC ACID (MONOHYDRATE USP)	8.0 mg
		3	DIBUTYL SEBACATE NF	9.6 mg
		4	ETHANOL USP 99.9 Percent	2.62 ml
		5	100CC WHITE HDPE BOTTLE WITH 38MM NECK DB-02 TRIVENI PLASTIC	Relevant, as per packing policy
		6	38/400 FG, CRC HAVING UNIPAC SG-75M LINER PTD. WITH SFYP IN BLACK (REXAM CLOSURES)	

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

Case No.	104 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004630AM23
RA File Number	03AX04004100 AM23
Licence No and Date	0311019554/28/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jul/202324/9 dated 28.07.2023** against advance authorization No. **0311016511 dt. 22.07.2022**, 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. applied.
BELGUARD PBSA (Phenyl benzimidazole Sulfonic Acid).	1 kg.	1	Ortho Phenylene Diamine	0.4925 kg.

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

Case No.	105 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004638AM23
RA File Number	31AX04000235 AM23
Licence No and Date	3111001845/28/11/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 93.60% W/W WHITE GRANULES POWDER	1 kg.	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.522 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	106 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004644AM23
RA File Number	09AX04000725 AM23
Licence No and Date	0911004033/28/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Sep/202324/13 dated 14/09/2023** against advance authorization **No. 0911005348 dated 06/07/2023**, 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.
ERDOSTEINE	1 kg.	1	DL-Homocysteine thiolactone HCl	0.89 kg.
		2	Thiodi glycolic Acid	0.81 kg.

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

Case No.	107 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004648AM23
RA File Number	09AX04000768 AM23
Licence No and Date	0911004035/28/11/2022

Norms Committee Decision:

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

Case No.	108 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004663AM23
RA File Number	03AX04004308 AM23
Licence No and Date	0311019588/29/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	109 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004666AM23
RA File Number	08AX04001437 AM23
Licence No and Date	0811006586/29/11/2022
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.	110 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004680AM23
RA File Number	05AX04002461 AM23
Licence No and Date	0511016086/29/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No. 0511012794 dated 25/05/2022 , 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:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TELMISARTAN CRUDE (POWDER)	1 kg.	1	2-n-propyl-4-methyl-6-(1-methylbenzimidazol-2-yl)	0.57 kg.
		2	2-Cyano-4-Methyl Biphenyl (OTBN)	0.65 kg.
		3	Acetic Acid	0.824 kg.
		4	Toluene	1.57 kg.
		5	Methylene Chloride	1.83 kg.
		6	Methanol	1.83 kg.

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

Case No.	111 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004687AM23
RA File Number	09AX04000763 AM23
Licence No and Date	0911004042/29/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	112 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004688AM23
RA File Number	09AX04000724 AM23
Licence No and Date	0911004047/29/11/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Sep/202324/13 dated 14/09/2023** against advance authorization **No. 0911005348 dated 06/07/2023**, 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.
ERDOSTEINE	1 kg.	1	DL-Homocysteine thiolactone HCl	0.89 kg.
		2	Thiodi glycolic Acid	0.81 kg.
		3	Methanol	1.00 kg.

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

Case No.	113 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004689AM23
RA File Number	08AX04001385 AM23
Licence No and Date	0811006590/29/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No. 0811008079 dated 03/05/2023**, 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.
PROPAFENONE TABLETS 150MG (PROPAFENON 150 HEUMANN)(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 150 MG NET CONTENT OF PROPAFENONE HYDROCHLORIDE EP SHOULD NOT BE LESS THAN 253.800 KGS. IN EXPORT ITEM)	1 NUMBER	1	PROPAFENONE HYDROCHLORIDE EP	153 mg/ tablet

PROPAFENONE TABLETS 300MG (PROPAFENON 300 HEUMANN)(EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 300 MG NET CONTENT OF PROPAFENONE HYDROCHLORIDE EP SHOULD NOT BE LESS THAN 528.000 KGS. IN EXPORT ITEM)	1 NUMBER	2	PROPAFENONE HYDROCHLORIDE EP	306 mg/ tablet
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RA concerned may take further necessary action as per above decision of NC.

Case No.	114 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004690AM23
RA File Number	34AX04000779 AM23
Licence No and Date	3411003057/29/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Mar/202223/22 dated 24.03.2023** against advance authorization No. **3411003057 dated 29.11.2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol.1 as per details given below or as applied by the firm, whichever is less:-

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. allowed
1	Desipramine HCL Tab USP 10 mg (Desipramine HCL Tab USP 10 mg (net content of active ingredients = 4.00 kgs))	1 Number Tablet	1	Desipramine Hydrochloride USP	10.20 mg
			2	Croscarmellose Sodium (Ac-di-sol)	3.50 mg
			3	Microcrystalline cellulose (Avicel PH102)	13.41 mg
			4	Hydroxypropyl Cellulose (Klucel LF)	0.28 mg

			5	Citric Acid Monohydrate (Powder Emprove)	0.67 mg
			6	Magnesium Stearate	0.14 mg
2	Desipramine HCL Tab USP 25 mg (Desipramine HCL Tab USP 25 mg (net content of active ingredients = 10.00 kgs))	1 Number Tablet	1	Desipramine Hydrochloride USP	25.50 mg
			2	Croscarmellose Sodium (Ac-di-sol)	8.75 mg
			3	Microcrystalline cellulose (Avicel PH102)	33.53 mg
			4	Hydroxypropyl Cellulose (Klucel LF)	0.70 mg
			5	Citric Acid Monohydrate (Powder Emprove)	1.67 mg
			6	Magnesium Stearate	0.35 mg
3	Desipramine HCL Tab USP 50 mg (Desipramine HCL Tab USP 50 mg (net content of active ingredients = 25.00 kgs))	1 Number Tablet	1	Desipramine Hydrochloride USP	51.00 mg
			2	Croscarmellose Sodium (Ac-di-sol)	17.50 mg
			3	Microcrystalline cellulose (Avicel PH102)	67.07 mg
			4	Hydroxypropyl Cellulose (Klucel LF)	1.40 mg
			5	Citric Acid Monohydrate (Powder Emprove)	3.33 mg
			6	Magnesium Stearate	0.70 mg
4	Desipramine HCL Tab USP 75 mg (Desipramine HCL Tab USP 75 mg (net content of active ingredients = 37.50 kgs))	1 Number Tablet	1	Desipramine Hydrochloride USP	76.50 mg
			2	Croscarmellose Sodium (Ac-di-sol)	26.25 mg
			3	Microcrystalline cellulose (Avicel PH102)	100.60 mg

	kgs))		4	Hydroxypropyl Cellulose (Klucel LF)	2.10 mg
			5	Citric Acid Monohydrate (Powder Emprove)	5.00 mg
			6	Magnesium Stearate	1.05 mg
5	Desipramine HCL Tab USP 100 mg (Desipramine HCL Tab USP 100 mg (net content of active ingredients = 50.00 kgs))	1 Number Tablet	1	Desipramine Hydrochloride USP	102.00 mg
			2	Croscarmellose Sodium (Ac-di-sol)	35.00 mg
			3	Microcrystalline cellulose (Avicel PH102)	134.13 mg
			4	Hydroxypropyl Cellulose (Klucel LF)	2.80 mg
			5	Citric Acid Monohydrate (Powder Emprove)	6.67 mg
			6	Magnesium Stearate	1.40 mg
6	Desipramine HCL Tab USP 150 mg (Desipramine HCL Tab USP 150 mg (net content of active ingredients = 60.000 kgs))	1 Number Tablet	1	Desipramine Hydrochloride USP	153.00 mg
			2	Croscarmellose Sodium (Ac-di-sol)	52.50 mg
			3	Microcrystalline cellulose (Avicel PH102)	201.20 mg
			4	Hydroxypropyl Cellulose (Klucel LF)	4.20 mg
			5	Citric Acid Monohydrate (Powder Emprove)	10.00 mg
			6	Magnesium Stearate	2.10 mg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	115 / NC/3/MEET/Dec/202324/19
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Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004723AM23
RA File Number	09AX04000639 AM23
Licence No and Date	0911004062/30/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202324/14 dated 27.09.2023** against advance authorization No. **0911005462 dated 21.07.2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol.1 as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed
5-Hydroxy-1,3-oxathiolane-2-carboxylicacid (1R,2S,5R) menthyl ester	1 kg	1	Glyoxylic acid 50%	0.69 kg
		2	Sodium bisulphite	0.55 kg
		3	2,5-dihydroxy-1,4-dithiane	0.28 kg
		4	Formaldehyde	0.46 kg
		5	N-Hexane	0.44 kg
		6	Toluene	0.22 kg
		7	Cyclohexane	0.55 kg
		8	L-(-) Menthol 99%	0.725 kg

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

Case No.	116 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024

and Date	
HQ File Number	HQRNORM APPLY 00004725AM23
RA File Number	09AX04000586 AM23
Licence No and Date	0911004061/30/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202324/14 dated 27.09.2023** against advance authorization No. **0911005462 dated 21.07.2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol.1 as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
5-Hydroxy-1,3-oxathiolane-2-carboxylicacid (1R,2S,5R) menthyl ester	1 kg	1	Glyoxylic acid 50%	0.69 kg
		2	Sodium bisulphite	0.55 kg
		3	2,5-dihydroxy-1,4-dithiane	0.28 kg
		4	Formaldehyde	0.46 kg
		5	N-Hexane	0.44 kg
		6	Toluene	0.22 kg
		7	Cyclohexane	0.55 kg
		8	L-(-) Menthol 99%	0.725 kg

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

Case No.	117 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004726AM23
RA File Number	03AX04004382 AM23

Licence No and Date	0311019654/01/12/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jul/202324/9 dated 28.07.2023 against advance authorization No. 0311014646 dated 11.05.2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol.1 as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PDSH(PDSH TECHNICAL)	1 kg.	1	2 FLURO A NILINE	0.66 kg.
		2	ETHYL CHLOROFORMATE	0.55 kg.
		3	DI METHYL FORMAMIDE	Deleted (not given in production/consumption data & also not a main reactant
		4	ETHYL 3 AMINO 4 4 4 TRIFLUROCROTONATE	0.66 kg.
		5	POTASSIUM CARBONATE	0.31 kg.

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

Case No.	118 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004728AM23
RA File Number	03AX04004201 AM23
Licence No and Date	0311019658/01/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	119 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024																									
HQ File Number	HQRNORM APPLY 00004745AM23																									
RA File Number	04AX04000794 AM23																									
Licence No and Date	0411004556/01/12/2022																									
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/202324/8 dated 30.06.2023 against advance authorization No. 0411005200 dated 06/04/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <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="5">IBUPROFEN</td> <td rowspan="5">1 Kg.</td> <td>1</td> <td>ISOBUTYL ACETOPHENONE</td> <td>1.110 kg.</td> </tr> <tr> <td>2</td> <td>SODIUM METAL</td> <td>0.235 kg.</td> </tr> <tr> <td>3</td> <td>MONOCHLORO ACETIC ACID</td> <td>0.919 kg.</td> </tr> <tr> <td>4</td> <td>ISO PROPYL ALCOHOL</td> <td>0.500 kg.</td> </tr> <tr> <td>5</td> <td>SODIUM DICHROMATE</td> <td>0.630 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	IBUPROFEN	1 Kg.	1	ISOBUTYL ACETOPHENONE	1.110 kg.	2	SODIUM METAL	0.235 kg.	3	MONOCHLORO ACETIC ACID	0.919 kg.	4	ISO PROPYL ALCOHOL	0.500 kg.	5	SODIUM DICHROMATE	0.630 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed																						
IBUPROFEN	1 Kg.	1	ISOBUTYL ACETOPHENONE	1.110 kg.																						
		2	SODIUM METAL	0.235 kg.																						
		3	MONOCHLORO ACETIC ACID	0.919 kg.																						
		4	ISO PROPYL ALCOHOL	0.500 kg.																						
		5	SODIUM DICHROMATE	0.630 kg.																						

Case No.	120 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004771AM23
RA File Number	03AX04004397 AM23
Licence No and Date	0311019716/02/12/2022
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No. 0311019716 dated 02/12/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Export product	Qty.	Sl. No.	Import items	Qty. allowed
FLUTICASONE LOTION 0.05% (Fluticasone Propionate Lotion 0.05%) (Pack 60 ML)((Net wt. of Fluticasone Propionate USP is 1.50 Kgs.))	50000 Numbers	1	Fluticasone Propionate USP	1.53 kg

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

Case No.	121 / NC/3/MEET/Dec/202324/19													
Case Status	Case Approved													
Party Name	FDC LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024													
HQ File Number	HQRNORM APPLY 00004788AM23													
RA File Number	03AX04004005 AM23													
Licence No and Date	0311019730/02/12/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: -														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>CHLORAMPHENICOL EYE DROPS 10552000.0 ML((EACH VIAL CONTAINS CHLORAMPHENICOL MICRONIZED 0.050GM NET WT OF BULK DRUG IS 27.600 KGS))</td><td>Numbers</td><td>1</td><td>CHLORAMPHENICOL MICRONIZED</td><td>28.152 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CHLORAMPHENICOL EYE DROPS 10552000.0 ML((EACH VIAL CONTAINS CHLORAMPHENICOL MICRONIZED 0.050GM NET WT OF BULK DRUG IS 27.600 KGS))	Numbers	1	CHLORAMPHENICOL MICRONIZED	28.152 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
CHLORAMPHENICOL EYE DROPS 10552000.0 ML((EACH VIAL CONTAINS CHLORAMPHENICOL MICRONIZED 0.050GM NET WT OF BULK DRUG IS 27.600 KGS))	Numbers	1	CHLORAMPHENICOL MICRONIZED	28.152 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	122 / NC/3/MEET/Dec/202324/19			
Case Status	Case Deferred			
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM APPLY 00004798AM23			
RA File Number	03AX04004191 AM23			

Licence No and Date	0311019737/03/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	123 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004807AM23
RA File Number	03AX04004440 AM23
Licence No and Date	0311019755/05/12/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	124 / NC/3/MEET/Dec/202324/19													
Case Status	Case Approved													
Party Name	RAVOO'S LABORATORIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024													
HQ File Number	HQRNORM APPLY 00004812AM23													
RA File Number	09AX04000761 AM23													
Licence No and Date	0911004086/05/12/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: -														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. Allowed</th></tr><tr><td>Ciprofloxacin Hydrochloride Taste Masked Pellets (Ciprofloxacin HCL USP NET CONTENT 10991.20 KG)</td><td>50000 kg.</td><td>1</td><td>Ciprofloxacin HCL USP</td><td>10991.20 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed	Ciprofloxacin Hydrochloride Taste Masked Pellets (Ciprofloxacin HCL USP NET CONTENT 10991.20 KG)	50000 kg.	1	Ciprofloxacin HCL USP	10991.20 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. Allowed										
Ciprofloxacin Hydrochloride Taste Masked Pellets (Ciprofloxacin HCL USP NET CONTENT 10991.20 KG)	50000 kg.	1	Ciprofloxacin HCL USP	10991.20 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	125 / NC/3/MEET/Dec/202324/19
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Case Status	Case Approved													
Party Name	INDO AMINES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024													
HQ File Number	HQRNORM REVIW00001065AM24													
RA File Number	03AX04004219 AM23													
Licence No and Date	0311019745/05/12/2022													
Norms Committee Decision:														
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed</th></tr><tr><td>SORBITAN MONO OLEATE OR IAL SMO</td><td>1 Kg.</td><td>1</td><td>SORBITOL 70%</td><td>0.50 Kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	SORBITAN MONO OLEATE OR IAL SMO	1 Kg.	1	SORBITOL 70%	0.50 Kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed										
SORBITAN MONO OLEATE OR IAL SMO	1 Kg.	1	SORBITOL 70%	0.50 Kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	126 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AURORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004828AM23
RA File Number	09AX04000798 AM23
Licence No and Date	0911004095/06/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	127 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004836AM23
RA File Number	03AX04004351 AM23
Licence No and Date	0311019783/06/12/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/8 dated 23.09.2022** against advance authorization No. **0311007434 dated 03.10.2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export Product	Qty.	Import items	Qty. allowed
1	FLUCORT N SKIN CREAM 0.025% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 1.210 Kgs.)	322660 Packs	FLUOCINOLONE ACETONIDE BP	9.10 kg
2	FLUCORT SKIN CREAM 0.025% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 1.210 Kgs.)	322660 Packs		
3	FLUCORT SKIN CREAM 0.025% (Pack Size 10 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.605 Kgs.)	242000 Packs		
4	FLUCORT SKIN CREAM 0.025% (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 1.210 Kgs.)	968000 Packs		
5	FLUOCINOLONE CREAM (TDR) ET 0.025% (Pack Size 10 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	96800 Packs		
6	CYNOZET CREAM 0.025% (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	193600 Packs		
7	CYNOZET CREAM 0.025% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	64532 Packs		
8	SUPRICORT CREAM 0.025% (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.726 Kgs.)	580800 Packs		
9	SUPRICORT CREAM 0.025% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.726 Kgs.)	193596 Packs		
10	SUPRICORT CREAM 0.025% (Pack Size 250 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	3873 Packs		
11	SUPRICORT N CREAM 0.025% (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	193600 Packs		

12	SUPRICORT N CREAM 0.025% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242Kgs.)	64532 Packs		
13	Flucort C Cream 0.01% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.095 Kgs)	63332 Packs		
14	FLUCORT C OINTMENT 0.025% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.605 Kgs.)	161330 Packs		
15	GLENCORT GEL 0.025% (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.452 Kgs.)	361600 Packs		
16	GLENCORT GEL 0.025% (Pack Size 30 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.484 Kgs.)	64535 Packs		
17	FLUCORT MZ SKIN OINTMENT 0.01% (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.145 Kgs.)	96798 Packs		
RA concerned may take further necessary action as per above decision of NC				

Case No.	128 / NC/3/MEET/Dec/202324/19			
Case Status	Case Approved			
Party Name	TRANSPEK INDUSTRY LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM APPLY 00004865AM23			
RA File Number	34AX04000797 AM23			
Licence No and Date	3411003093/07/12/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NEODECANOYL CHLORIDE	1 kg.	1	N-DECANOIC ACID	0.950 kg.

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

Case No.	129 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00005141AM24
RA File Number	08AX04001419 AM23
Licence No and Date	0811006678/07/12/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	130 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00004943AM23
RA File Number	03AX04004593 AM23
Licence No and Date	0311019936/12/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	131 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	B G P HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005000AM23
RA File Number	34AX04000827 AM23
Licence No and Date	3411003121/15/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	132 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005018AM23
RA File Number	09AX04000828 AM23
Licence No and Date	0911004164/15/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	133 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005075AM23
RA File Number	03AX04004710 AM23
Licence No and Date	0311020115/19/12/2022

Norms Committee Decision:

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

Sl.No	Export Product	Quantity
(i)	Medical Creams & Ointments(Clindamycin Phosphate Topical Solution USP 1 % (60 ML) Tot Wt: 2455.20 Kgs (Net Cont: CLINDA 31.43Kgs, 2 Oz. HDPE 440000Nos, 24-400 WHITE PP 440000Nos, DAB-O-MATIC 440000Nos.))	1 Number
(ii)	Medical Creams & Ointments(Clindamycin Phosphate Topical Solution USP 1 % (30 ML) Tot Wt: 1227.60Kgs (Net Cont: CLINDA 15.71Kgs, 1 Oz. HDPE 44000Nos, 24-400 WHITE PP 44000Nos, DAB-O-MATIC 44000Nos.))	1 Number
(iii)	Medical Creams & Ointments(Clindamycin Phosphate & Benzoyl Peroxide Gel, 1.2%/5% (45 Gm) Tot Wt: 45 Kgs (Net Cont: CLINDA 0.54 Kgs, HYDROUS BENZ 2.25 Kgs.Tubes 1000Nos))	1 Number
(iv)	Medical Creams & Ointments(Clindamycin Phosphate Top. Lot. 1% 60ML Tot Wt: 55.80 Kgs (Net Cont: CLINDA 0.66 Kgs, STEARIC ACID 1.12 Kgs, KOLLIWAX CSA 1.40Kgs, LDPE BOTTLE 1000 Nos))	1 Number
(v)	Medical Creams & Ointments(Clindamycin Phosphate Gel 30 Gm Tot Wt: 30 Kgs (Net	1 Number

	Cont: CLINDA 0.36Kgs, Tubes 1000Nos.))	
(vi)	Medical Creams & Ointments(Clindamycin Phosphate Gel 60 Gm Tot Wt: 60 Kgs (Net Cont: CLINDA 0.71Kgs, Tubes 1000 Nos.))	1 Number
(vii)	Medical Creams & Ointments(Clindamycin 10mg/g + Benzoyl Peroxide 50mg/g Gel 30Gm Tot Wt: 30 Kgs (Net Cont: CLINDA 0.30 Kgs, BENZOYL 1.50 Kgs, Tubes 1000 Nos))	1 Number
(viii)	Medical Creams & Ointments(Clindamycin 10mg/g + Benzoyl Peroxide 50mg/g Gel 60 Gm Tot Wt: 60 Kgs (Net Cont: CLINDA 0.60 Kgs, BENZOYL 4.28 Kgs, Tubes 1000 Nos))	1 Number

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

Note:

1. **1.03 kg.** of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**
2. **1.02 kg.** of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**
3. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	134 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SHARON BIO-MEDICINE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM APPLY 00005222AM23			
RA File Number	03AX04004798 AM23			
Licence No and Date	0311020213/22/12/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBI 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.
DIARRHOEA RELIEF INSTANT 2MG ORODISPERSIBLE TABLETS / LOPERAMIDE 2MG FAST MELT TABLETS 6's (DIARRHOEA RELIEF INSTANT 2MG(ORODISPERSIBLE TABLETS / LOPERAMIDE 2MG FAST MELT TAB 6's) Each Tablets contains PHARMABURST B1 184 Kgs for One Batch equal to 10,00,000 Tablets) (PHARMABURST B1 1075.22 Kgs equal to 5843592 Tablets) NET WT. LOPERAMIDE HYDROCHLORIDE PH EUR 11.69 KGS)	1 NUMBER	1	PHARMABURST B1	184.00 mg
		2	LOPERAMIDE HYDROCHLORIDE PH EUR	2.04 mg

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

Case No.	135 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005247AM23
RA File Number	08AX04001457 AM23
Licence No and Date	0811006828/23/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	136 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	KAVALIFE PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024

and Date				
HQ File Number	HQRNORM APPLY 00005283AM23			
RA File Number	07AX04001408 AM23			
Licence No and Date	0711006001/26/12/2022			
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 1/82-ALC4/2019 dated 03/06/2019 against advance authorization No. 0710113301 dated 17/05/2018 , 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:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Natural Caffeine Anhydrous (Not less than 98.5%)	1 kg.	1	Natural Caffeine Powder 98.5%	1.186 kg.

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

Case No.	137 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005300AM23
RA File Number	09AX04000869 AM23
Licence No and Date	0911004207/26/12/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	138 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005311AM23
RA File Number	03AX04004688 AM23
Licence No and Date	0311020288/27/12/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Oct/202324/15 dated 13/10/2023 against advance authorization No. 0311004745 dated 19/06/2021, 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.
MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE) [Containing NLT 84% Sterile Meropenem]	1 kg.	1	MEROPENEM NON STERILE MEROPENEM TRIHYDRATE NON STERILE	0.8968 kg.
		2	Packing Material	Relevant, as per Packing Policy

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

Case No.	139 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005317AM23
RA File Number	07AX04001362 AM23
Licence No and Date	0711006024/27/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	140 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	CANPEX CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005335AM23
RA File Number	31AX04000284 AM23
Licence No and Date	3111001917/27/12/2022
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	

1. Complete CoA of import item from Foreign Supplier

Case No.	141 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	INDIA GLYCOLS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005340AM23
RA File Number	05AX04002859 AM23
Licence No and Date	0511016572/27/12/2022

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/202324/5 dated 08/06/2023** against advance authorization **No. 0511013942 dated 25/07/2022**, 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.
Mono Ethylene Glycol (MEG)	1 kg.	1	Denatured Ethyl Alcohol	1.123 kg.
		2	Silver Catalyst (Activity 17% to 18%)	0.000228 kg.
		3	Alumina Catalyst	0.000362 kg.

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

Case No.	142 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005381AM23
RA File Number	07AX04001433 AM23
Licence No and Date	0711006048/28/12/2022

Norms Committee Decision:

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

Case No.	143 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005387AM23
RA File Number	05AX04002796 AM23
Licence No and Date	0511016607/28/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	144 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005401AM23
RA File Number	34AX04000903 AM23
Licence No and Date	3411003211/29/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	145 / NC/3/MEET/Dec/202324/19				
Case Status	Case Approved				
Party Name	VINYL PRODUCTS PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024				
HQ File Number	HQRNORM APPLY 00005409AM23				
RA File Number	05AX04002878 AM23				
Licence No and Date	0511016621/29/12/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.

PVC Plasticizer (Phthalic, Non-Polymeric)	1 kg.	1	PHTHALIC ANHYDRIDE	0.400 kg.
		2	2 ETHYL HEXANOL	0.700 kg.

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

Case No.	146 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	COHANCE LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005417AM23
RA File Number	09AX04000884 AM23
Licence No and Date	0911004233/29/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	147 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	COHANCE LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005432AM23
RA File Number	09AX04000883 AM23
Licence No and Date	0911004235/30/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	148 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005442AM23
RA File Number	05AX04002802 AM23
Licence No and Date	0511016635/30/12/2022
Norms Committee Decision:	

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

Case No.	149 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005480AM23
RA File Number	03AX04004595 AM23
Licence No and Date	0311020433/03/01/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jul/202324/9 dated 28.07.2023** against advance authorization No. **0311016511 dt. 22.07.2022**, 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.
BELGUARD PBSA (Phenyl benzimidazole Sulfonic Acid).	1 kg.	1	Ortho Phenylene Diamine	0.4925 kg.

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

Case No.	150 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005487AM23
RA File Number	30AX04000416 AM23
Licence No and Date	3011002973/03/01/2023

Norms Committee Decision:

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

Case No.	151 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	RAKSHIT DRUGS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024

and Date	
HQ File Number	HQRNORM APPLY 00005513AM23
RA File Number	09AX04000866 AM23
Licence No and Date	0911004255/04/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	152 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005526AM23
RA File Number	09AX04000891 AM23
Licence No and Date	0911004257/04/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	153 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005545AM23
RA File Number	07AX04001477 AM23
Licence No and Date	0711006102/05/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	154 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	BIODEAL PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005558AM23
RA File Number	05AX04002932 AM23
Licence No and Date	0511016743/05/01/2023
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NASAL SPRAY(PUMP-90-APF-SNAP-20-26. 0-360 DEGREE NASAL ADAPTOR WITH CHEMICALS AS PER THE DRUG LICENSE)	148500 pieces	1	NASAL ADAPTOR	Relevant on Net-to-Net basis with accountability.

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

Case No.	155 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005568AM23
RA File Number	34AX04000926 AM23
Licence No and Date	3411003231/05/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	156 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005588AM23
RA File Number	05AX04002947 AM23
Licence No and Date	0511016763/06/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	157 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved

Party Name	MICRO LABS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024										
HQ File Number	HQRNORM APPLY 00005595AM23										
RA File Number	07AX04001473 AM23										
Licence No and Date	0711006137/06/01/2023										
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Nov/202324/16 dated 17.11.2023 against advance authorization No. 0711004103 dt. 26.05.2022, 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 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>PHLOROGLUCINOL 160MG ODT</td><td>1 Number</td><td>1</td><td>PHLOROGLUCINOL DIHYDRATE</td><td>163.20 mg</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PHLOROGLUCINOL 160MG ODT	1 Number	1	PHLOROGLUCINOL DIHYDRATE	163.20 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
PHLOROGLUCINOL 160MG ODT	1 Number	1	PHLOROGLUCINOL DIHYDRATE	163.20 mg							

Case No.	158 / NC/3/MEET/Dec/202324/19															
Case Status	Case Approved															
Party Name	CIPLA LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024															
HQ File Number	HQRNORM REVIW00002991AM24															
RA File Number	03AX04004890 AM23															
Licence No and Date	0311020522/06/01/2023															
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jan/202122/13 dated 21/01/2022 against advance authorization No.0311005784 dated 01/08/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Sl. No.</th><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</td><td rowspan="2">Telmisartan and Amlodipine Tablets 40/10mg / Each uncoated tablets contains :(Telmisartan 40 mg Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to</td><td rowspan="2">1 Number</td><td>1</td><td>Telmisartan Granules</td><td>68.034 mg</td></tr> <tr> <td>2</td><td>Amlodipine Besilate</td><td>10.20 mg</td></tr> </tbody> </table>		Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. allowed	1	Telmisartan and Amlodipine Tablets 40/10mg / Each uncoated tablets contains :(Telmisartan 40 mg Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to	1 Number	1	Telmisartan Granules	68.034 mg	2	Amlodipine Besilate	10.20 mg
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. allowed											
1	Telmisartan and Amlodipine Tablets 40/10mg / Each uncoated tablets contains :(Telmisartan 40 mg Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to	1 Number	1	Telmisartan Granules	68.034 mg											
			2	Amlodipine Besilate	10.20 mg											

	Amlodipine USP 10mg Net wt of Telmisartan Granules is 2020.800 Kgs. Net wt of Amlodipine Besilate is 300.000 Kgs.)				
2	Telmisartan and Amlodipine Tablets 80/10mg / Each uncoated tablets contains : Telmisartan 80 mg(Telmisartan 80 mg equivalent to Telmisartan granules 134.72mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is 10777.600 Kgs. Net wt of Amlodipine Besilate is 800.000 Kgs.)	1 Number	3	Telmisartan Granules	136.07 mg
			4	Amlodipine Besilate	10.20 mg
3	Telmisartan and Amlodipine Tablets 40/5mg / Each uncoated tablets contains : Telmisartan 40 mg(Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 5mg Net wt of Telmisartan Granules is 6286.933 Kgs. Net wt of Amlodipine Besilate is 466.667 Kgs.)	1 Number	5	Telmisartan Granules	68.034 mg
			6	Amlodipine Besilate	5.10 mg
4	Telmisartan and Amlodipine Tablets 80/5mg / Each uncoated tablets contains : Telmisartan 80 mg(Telmisartan 80 mg equivalent to Telmisartan granules 134.72mg Amlodipine Besilate equivalent to Amlodipine USP 5mg Net wt of Telmisartan Granules is 10777.600 Kgs. Net wt of Amlodipine Besilate is 400.000 Kgs.)	1 Number	7	Telmisartan Granules	136.07 mg
			8	Amlodipine Besilate	5.10 mg

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

Case No.	159 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005679AM23
RA File Number	08AX04001685 AM23
Licence No and Date	0811006983/11/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	160 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005687AM23
RA File Number	31AX04000281 AM23
Licence No and Date	3111001952/12/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	161 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	PRACHI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005760AM23
RA File Number	03AX04005177 AM23
Licence No and Date	0311020750/16/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	162 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005762AM23
RA File Number	08AX04001684 AM23
Licence No and Date	0811007029/16/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	163 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00004701AM24
RA File Number	07AX04001546 AM23
Licence No and Date	0711006197/16/01/2023
Norms Committee Decision:	

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

Case No.	164 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005768AM23
RA File Number	05AX04003041 AM23
Licence No and Date	0511016882/17/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	165 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005769AM23
RA File Number	08AX04001660 AM23
Licence No and Date	0811007032/17/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	166 / NC/3/MEET/Dec/202324/19				
Case Status	Case Approved				
Party Name	SHARON BIO-MEDICINE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024				
HQ File Number	HQRNORM APPLY 00005790AM23				
RA File Number	03AX04005196 AM23				
Licence No and Date	0311020778/18/01/2023				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.

MICONAZOLE NITRATE	1 kg.	1	Alpha-(2,4-Dichlorophenyl)-1H-Imidazole-1-Ethanol	0.662 kg.
		2	2,4,Dichloro Benzyl Chloride	0.504 kg.

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

Case No.	167 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005804AM23
RA File Number	05AX04002999 AM23
Licence No and Date	0511016918/18/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	168 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	LYRUS LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00000961AM24
RA File Number	NA
Licence No and Date	0711006229/19/01/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. Drug Manufacturing Licence (DML)	
2. Master Batch Formula	

Case No.	169 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024

and Date	
HQ File Number	HQRNORM APPLY 00005814AM23
RA File Number	03AX04005159 AM23
Licence No and Date	0311020797/19/01/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Get the Advance Authorisation amended to show content of API in export in line with DML.	

Case No.	170 / NC/3/MEET/Dec/202324/19																						
Case Status	Case Approved																						
Party Name	ALEMBIC PHARMACEUTICALS LIMITED																						
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024																						
HQ File Number	HQRNORM APPLY 00005817AM23																						
RA File Number	34AX04000948 AM23																						
Licence No and Date	3411003270/19/01/2023																						
Norms Committee Decision:																							
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Mar/202223/22 dated 24.03.2023 against advance authorization No. 3411002918 dt. 17.10.2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:																							
<table><tr><td>Sl. No.</td><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty. (in grams)</td></tr><tr><td>1</td><td>Diclofenac Sodium Topical Solution 2 % 112 gm</td><td>1 number</td><td>1</td><td>Diclofenac Sodium USP</td><td>2.2838</td></tr><tr><td>2</td><td>Diclofenac Sodium Topical Gel 3 % 100 gm</td><td>1 number</td><td>2</td><td>Diclofenac Sodium USP</td><td>3.06</td></tr></table>						Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. (in grams)	1	Diclofenac Sodium Topical Solution 2 % 112 gm	1 number	1	Diclofenac Sodium USP	2.2838	2	Diclofenac Sodium Topical Gel 3 % 100 gm	1 number	2	Diclofenac Sodium USP	3.06
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. (in grams)																		
1	Diclofenac Sodium Topical Solution 2 % 112 gm	1 number	1	Diclofenac Sodium USP	2.2838																		
2	Diclofenac Sodium Topical Gel 3 % 100 gm	1 number	2	Diclofenac Sodium USP	3.06																		
RA concerned may take further necessary action as per above decision of NC.																							

Case No.	171 / NC/3/MEET/Dec/202324/19
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Case Status	Case Deferred
Party Name	LYRUS LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005820AM23
RA File Number	07AX04001513 AM23
Licence No and Date	0711006229/19/01/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Drug Manufacturing Licence (DML) 2. Master Batch Formula	

Case No.	172 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005825AM23
RA File Number	05AX04003069 AM23
Licence No and Date	0511016941/19/01/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	173 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	MICROTROL STERILISATION SERVICES PVT.LTD.
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005834AM23
RA File Number	07AX04001525 AM23
Licence No and Date	0711006236/19/01/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	174 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved

Party Name	LECILITE INGREDIENTS PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024				
HQ File Number	HQRNORM APPLY 00005848AM23				
RA File Number	50AX04000092 AM23				
Licence No and Date	5011000769/20/01/2023				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.
RAPSEED LECITHIN POWDER / GRANULES		1 kg.	1	RAPSEED LECITHIN	1.40 kg.
RA concerned may take further necessary action as per above decision of NC.					

Case No.	175 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SUMAR BIOTECH LLP
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005852AM23
RA File Number	02AX04000593 AM23
Licence No and Date	0211003713/20/01/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
Complete technical details as per Annexure to Appendix-4E.	

Case No.	176 / NC/3/MEET/Dec/202324/19			
Case Status	Case Deferred			
Party Name	MEGHMANI INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM APPLY 00005857AM23			
RA File Number	08AX04001681 AM23			
Licence No and	0811007072/21/01/2023			

Date	
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	177 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	AARTI PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005863AM23
RA File Number	03AX04005211 AM23
Licence No and Date	0311020885/23/01/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Oct/202122/9 dated 15.10.2021** against advance authorization No. **0310838954 dt. 16.10.2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty. approved.
BUDESONIDE	1 kg	1	16 ALPHA HYDROXY PREDNISOLONE	0.972 kg

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

Case No.	178 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005864AM23
RA File Number	03AX04005046 AM23
Licence No and Date	0311020890/23/01/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09.09.2022** against advance authorization No. **0311010761 dt. 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. allowed.

1	Nifedipine Extended-Release Tablets 30mg.(Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 56.80 mg (ii)Eastman(TMCelluloseAcetate(CA398-10NF/EP)- 33.12mg (iii) SENTRY POLYOX WSR N80 FPNF- 118.40mg.Netcontent (i)1382 Kgs (ii) 805.84 Kgs (iii) 2880.79 Kgs.)	1 Number	1	SENTRY POLYOX WSR COAGULANT NF	56.8 mg
			2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	33.12 mg
			3	SENTRY POLYOX WSR N80 FP NF	118.40 mg
2	Nifedipine Extended-Release Tablets 60mg.(Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 113.60 mg (ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 42.32 mg (iii) SENTRY POLYOX WSR N80 FP NF - 236.80 mg. Net content (i) 650 Kgs (ii) 242.15 Kgs (iii) 1354.93 Kgs)	1 Number	4	SENTRY POLYOX WSR COAGULANT NF	113.60 mg
			5	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	42.32 mg
			6	SENTRY POLYOX WSR N80 FP NF	236.80 mg

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

Case No.	179 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005868AM23
RA File Number	07AX04001590 AM23
Licence No and Date	0711006247/23/01/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sterile Water for Injection 10mL Vial(Sterile Water for injection, filled in 10mL Vial and capped with 13mm GreySerum	1 Numbers	1	13mm GraySerum Chlorobutyl R/S-RFS-C14226422GS6TP3	Relevant as per Packing Policy

Chlorobutyl Rubber Stopper)				
Sodium Chloride Injection USP 90mg per 10mL Vial(10mL Vial - filled with 90mg of Sodium Chloride as bulk drug filled in 10mL Vial and capped with 13mm GreySerum Chlorobutyl Rubber Stopper)	1 Numbers	2	13mm GraySerum Chlorobutyl R/S-RFS-C14226422GS6TP3	Relevant as per Packing Policy

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

Case No.	180 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005889AM23
RA File Number	09AX04000921 AM23
Licence No and Date	0911004310/24/01/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Methocarbamol	1 Kg.	1	Guaifenesin	1.05 kg.
		2	Sodium Methoxide Powder	0.005 kg.
		3	Dimethyl Carbonate	0.500 kg.
		4	Ammonium Chloride	0.015 kg.
		5	Ammonia Gas	0.250 kg.
		6	Toluene	0.300 kg.
		7	Methanol	0.700 kg.

		8	Activated carbon	0.005 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	181 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005897AM23
RA File Number	34AX04000965 AM23
Licence No and Date	3411003278/24/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	182 / NC/3/MEET/Dec/202324/19													
Case Status	Case Approved													
Party Name	RAVOO'S LABORATORIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024													
HQ File Number	HQRNORM APPLY 00005905AM23													
RA File Number	09AX04000930 AM23													
Licence No and Date	0911004357/24/01/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: -														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed</th></tr><tr><td>Ciprofloxacin Hydrochloride Taste Masked Pellets (Ciprofloxacin HCL USP NET CONTENT 1758.592 KG)</td><td>8000 kg.</td><td>1</td><td>Ciprofloxacin HCL USP</td><td>1758.592 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	Ciprofloxacin Hydrochloride Taste Masked Pellets (Ciprofloxacin HCL USP NET CONTENT 1758.592 KG)	8000 kg.	1	Ciprofloxacin HCL USP	1758.592 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed										
Ciprofloxacin Hydrochloride Taste Masked Pellets (Ciprofloxacin HCL USP NET CONTENT 1758.592 KG)	8000 kg.	1	Ciprofloxacin HCL USP	1758.592 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	183 / NC/3/MEET/Dec/202324/19
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Case Status	Case Approved
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005910AM23
RA File Number	05AX04003110 AM23
Licence No and Date	0511017012/25/01/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TELMISARTAN USP/BP/EP/JP/IP(Powder)	1kg.	1	2-n-propyl-4-methyl-6-(1-methylbenzimidazol-2-yl)	0.621 kg.
		2	2-Cyano-4-Methyl Biphenyl (OTBN)	0.650 kg.
		3	Acetic acid	0.90 kg.
		4	Toluene	1.71 kg.
		5	NButanol	1.34 kg.
		6	Methanol	1.25 kg.

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

Case No.	184 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SANJIVANI PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005920AM23
RA File Number	34AX04000896 AM23
Licence No and Date	3411003302/25/01/2023

Norms Committee Decision:

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

Case No.	185 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005935AM23
RA File Number	03AX04005248 AM23
Licence No and Date	0311020993/27/01/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Firm vide their letter dated 10.01.2023 have changed export description and export quantity (leading to change in import also). 2. The firm may be advised to furnish copy of Amended Licence, with export and import quantity and relevant details with DML.	

Case No.	186 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005943AM23
RA File Number	09AX04000960 AM23
Licence No and Date	0911004371/27/01/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	187 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005948AM23
RA File Number	34AX04000980 AM23
Licence No and Date	3411003310/28/01/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product /	

import item in Meeting No. **NC/3/MEET/Nov/202324/16 dated 17.11.2023** against advance authorization No. **3411002246 dt. 13.05.2022**, 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:

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MINOXIDIL TOPICAL AEROSOL 5% (FOAM) 60 Gm CAN (Net content of active ingredients 1350.00 kgs))	1 Number	1	MINOXIDIL USP	3.06 gm.

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

Case No.	188 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	LACTOSE (INDIA) LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005962AM23
RA File Number	03AX04005338 AM23
Licence No and Date	0311021031/30/01/2023

Norms Committee Decision:

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

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

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

Case No.	189 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024

and Date	
HQ File Number	HQRNORM APPLY 00005968AM23
RA File Number	03AX04005323 AM23
Licence No and Date	0311021042/30/01/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- “Get the license amended to show content of API in each export as per DML.”	

Case No.	190 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005989AM23
RA File Number	31AX04000316 AM23
Licence No and Date	3111001996/31/01/2023

Norms Committee Decision:

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

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty. allowed
(i)	Radicat Spot on 6% for Cats (Pack size 0.75ml x 6 pipettes),(Each ml contains: Selamectin BP 60mg, Net Weight = 810.00 Grams)	3000 Number	1	Selamectin BP / EP / USP	825 gm
(ii)	Radicat Spot on 6% for Cats (Pack size 0.75ml x 1 pipettes),(Each ml contains: Selamectin BP 60mg, Net Weight = 90.00 Grams)	2000 Number	2	Selamectin BP / EP / USP	92 gm
(iii)	Radicat Spot on 12% for Dog (Small Dog) (Pack size 0.5ml x 1 pipettes),(Each ml contains: Selamectin BP 12%, Net Weight = 102.00 Grams)	1700 Number	3	Selamectin BP / EP / USP	104 gm
(iv)	Radicat Spot on 12% for Dog (Medium Dog) (Pack	1600	4	Selamectin BP / EP /	195.8 gm

	size 1 ml x 1 pipettes),(Each ml contains: Selamectin BP 12%, Net Weight = 192.00 Grams)	Number		USP	
(v)	Radicat Spot on 12% for Dog (Large Dog) (Pack size 2 ml x 1 pipettes),(Each ml contains: Selamectin BP 12%, NetWeight = 360.00 Grams)	1500 Number	5	Selamectin BP / EP / USP	368 gm
(vi)	Radicat Spot on 12% for Dog (Extra Large Dog) (Pack size 3 ml x 1 pipettes),(Each ml contains: Selamectin BP 12%, Net Weight = 360.00 Grams)	1000 Number	6	Selamectin BP / EP / USP	368 gm

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

Case No.	191 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005991AM23
RA File Number	08AX04001832 AM23
Licence No and Date	0811007126/31/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	192 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00005992AM23
RA File Number	05AX04003132 AM23
Licence No and Date	0511017077/31/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	193 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024

HQ File Number	HQRNORM APPLY 00006001AM23
RA File Number	03AX04005245 AM23
Licence No and Date	0311021062/31/01/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	194 / NC/3/MEET/Dec/202324/19																									
Case Status	Case Approved																									
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED																									
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024																									
HQ File Number	HQRNORM APPLY 00006002AM23																									
RA File Number	04AX04000932 AM23																									
Licence No and Date	0411004841/31/01/2023																									
Norms Committee Decision:																										
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jun/202324/8 dated 30.06.2023 against advance authorization No. 0411005200 dated 06/04/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																										
<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="5">IBUPROFEN</td><td rowspan="5">1 Kg.</td><td>1</td><td>ISOBUTYL ACETOPHENONE</td><td>1.110 kg.</td></tr><tr><td>2</td><td>SODIUM METAL</td><td>0.235 kg.</td></tr><tr><td>3</td><td>MONOCHLORO ACETIC ACID</td><td>0.919 kg.</td></tr><tr><td>4</td><td>ISO PROPYL ALCOHOL</td><td>0.500 kg.</td></tr><tr><td>5</td><td>SODIUM DICHROMATE</td><td>0.630 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	IBUPROFEN	1 Kg.	1	ISOBUTYL ACETOPHENONE	1.110 kg.	2	SODIUM METAL	0.235 kg.	3	MONOCHLORO ACETIC ACID	0.919 kg.	4	ISO PROPYL ALCOHOL	0.500 kg.	5	SODIUM DICHROMATE	0.630 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed																						
IBUPROFEN	1 Kg.	1	ISOBUTYL ACETOPHENONE	1.110 kg.																						
		2	SODIUM METAL	0.235 kg.																						
		3	MONOCHLORO ACETIC ACID	0.919 kg.																						
		4	ISO PROPYL ALCOHOL	0.500 kg.																						
		5	SODIUM DICHROMATE	0.630 kg.																						
RA concerned may take further necessary action as per above decision of NC.																										

Case No.	195 / NC/3/MEET/Dec/202324/19			
Case Status	Case Deferred			
Party Name	FRESENIUS KABI ONCOLOGY LIMITED			
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			

and Date	
HQ File Number	HQRNORM APPLY 00006022AM23
RA File Number	05AX04003065 AM23
Licence No and Date	0511017109/01/02/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	196 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	CLAROID PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006027AM23
RA File Number	08AX04001720 AM23
Licence No and Date	0811007147/01/02/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	197 / NC/3/MEET/Dec/202324/19										
Case Status	Case Approved										
Party Name	KRITI NUTRIENTS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024										
HQ File Number	HQRNORM APPLY 00006034AM23										
RA File Number	56AX04000363 AM23										
Licence No and Date	5611001525/02/02/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-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>Soya Lecithin Liquid Food Grade (Non GMO)</td><td>1 MT</td><td>1</td><td>Crude Soya Lecithin Liquid</td><td>1.01 MT</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Soya Lecithin Liquid Food Grade (Non GMO)	1 MT	1	Crude Soya Lecithin Liquid	1.01 MT
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Soya Lecithin Liquid Food Grade (Non GMO)	1 MT	1	Crude Soya Lecithin Liquid	1.01 MT							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	198 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006043AM23
RA File Number	07AX04001666 AM23
Licence No and Date	0711006341/02/02/2023

Norms Committee Decision:

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. allowed.
1	OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION 0.1%W/V 5ML(EACH ML CONTAINS 1.11MG OF OLOPATADINE HYDROCHLORIDE (OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION 0.1%W/V 5ML EACH ML CONTAINS 1.11MG OF OLOPATADINE HYDROCHLORIDE 1060.05 GMS)	1 Number	1	OLOPATADINE HYDROCHLORIDE BP/EP/IP/USP	1081.251 gram
2	OLOPATADINE HYDROCHLORIDE (OPHTHALMIC SOLUTION 0.2 %W/V 2.5ML EACH ML CONTAINS 2.22MG OF OLOPATADINE HYDROCHLORIDE (OLOPATADINE HYDROCHLORIDE (OPHTHALMIC SOLUTION 0.2 %W/V 2.5ML EACH ML CONTAINS 2.22MG OF OLOPATADINE HYDROCHLORIDE 205.35 GMS)	1 Number	2	OLOPATADINE HYDROCHLORIDE BP/EP/IP/USP	209.457 gram

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

Case No.	199 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024

and Date	
HQ File Number	HQRNORM APPLY 00006048AM23
RA File Number	07AX04001667 AM23
Licence No and Date	0711006347/02/02/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	200 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006058AM23
RA File Number	03AX04005325 AM23
Licence No and Date	0311021126/03/02/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	201 / NC/3/MEET/Dec/202324/19													
Case Status	Case Approved													
Party Name	SHIVA BIO CHEM INDUSTRIES													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024													
HQ File Number	HQRNORM APPLY 00006072AM23													
RA File Number	50AX04000100 AM23													
Licence No and Date	5011000784/03/02/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Sunflower Lecithin (Liquid)</td><td>1 MT</td><td>1</td><td>Crude Sunflower Lecithin</td><td>1.01 MT</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sunflower Lecithin (Liquid)	1 MT	1	Crude Sunflower Lecithin	1.01 MT
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Sunflower Lecithin (Liquid)	1 MT	1	Crude Sunflower Lecithin	1.01 MT										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	202 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	CLARIANT INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00004661AM24
RA File Number	03AX04005405 AM23
Licence No and Date	0311021129/03/02/2023

Norms Committee Decision:

Ms. Meghana Abhijit Karpe, Logistic Head and Shri Prashant Wadaskar, Plant Manager of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PIROCTONE OLAMINE OR VIPIROX (Octopirox plus)	1 kg.	1	Dimethyl acrylic acid ester	0.84 kg.
		2	Hydroxyl amine hydrochloride	1.54 kg.
		3	Isononyl acid chloride	1.667 kg.
		4	Mono Ethanol Amine	0.241 kg.

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

Case No.	203 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006093AM23
RA File Number	09AX04000829 AM23
Licence No and Date	0911004417/06/02/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Sep/202324/13** dated **14/09/2023** against advance authorization

No. 0911005377 dated 11/07/2023, 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
(R)-9-[2-phosphonomethoxy propyl] Adenine (Compounds containing a pyrimidine ring (whether or not hydrogenated) or piperazine ring in the structure)	1 kg.	1	ADENINE	0.85 kg.
		2	N,N-DIMETHYLFORMAMIDE	2.00 kg.
		3	(R)-1,2-PROPYLENE CARBONATE	0.79 kg.
		4	N-METHYL-2-PYRROLIDONE	0.21 kg.
		5	Diethyl Para Toluene Sulfonyl Oxy Methyl Phosphonate	1.00 kg.
		6	Magnesium Tert. Butoxide	1.00 kg.

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

Case No.	204 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006101AM23
RA File Number	03AX04005404 AM23
Licence No and Date	0311021175/06/02/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. 5/82-ALC4/2020 dated 09/10/2020** against advance authorization **No. 0310834427 dated 23/01/2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import items	Qty. allowed
TADALAFIL	1 kg	1	(6R,12aR)-Methyl-1,2,3,4-tetrahydro-2-chloroacetyl-1-[3,4?-Methylene dioxyphenyl]-9H-pyrido- [3,4-b] indole-	1.64 kg

			3-carboxylate	
		2	METHANOL	7.14 kg

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

Case No.	205 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006103AM23
RA File Number	05AX04003187 AM23
Licence No and Date	0511017188/06/02/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	206 / NC/3/MEET/Dec/202324/19				
Case Status	Case Approved				
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024				
HQ File Number	HQRNORM APPLY 00006122AM23				
RA File Number	03AX04005303 AM23				
Licence No and Date	0311021200/07/02/2023				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jun/202324/6 dated 14/06/2023 against advance authorization No. 0311021547 dated 20/02/2023 , it was decided to fix adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export Product	Qty	Sl. No.	Import Items	Qty. allowed
1	Cetylpyridinium Chloride, Benzydamine Hydrochloride and Pholcodine Lozenges Sugar Free Blackcurrant/ Pineapple & Lime/(Honey, Lemon & Ginger/Other Flavours. Each Lozenge contains (i)Pholcodine 5.50mg (ii)Benzydamine Hydrochloride 1.50 mg(iii)Cetylpyridinium Chloride 1.33 mg (iv)Isomalt ST-M 2583 mg. Net Content (i) 43.80 kgs (ii) 11.94 kgs (iii) 10.59 kgs (iv) 20568)	1 Number	1	Pholcodine	5.61 mg
			2	Benzydamine Hydrochloride	1.53 mg
			3	Cetylpyridinium	1.357 mg

2	Pholcodine and Cetylpyridinium Chloride Lozenges Sugar Free Orange / Lemon and Other Flavours. (Each Lozenge contains (i)Pholcodine5.50mg(ii)CetylpyridiniumChloride1.33mg(iii)IsomaltST-M2579mg.NetContent(i)Pholcodine-30.77kg(ii)Cetylpyridinium Chloride-7.44 kg (iii) Isomalt ST-M-14427.96 kg.)	1 Number		Chloride	
			4	Isomalt ST-M	2583.0 mg
			5	Pholcodine	5.61 mg
			6	Cetylpyridinium Chloride	1.357 mg
			7	Isomalt ST-M	2579.0 mg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	207 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006123AM23
RA File Number	03AX04005375 AM23
Licence No and Date	0311021202/07/02/2023

Norms Committee Decision:

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

Sl.No	Export Product	Quantity
(i)	Medical cream and ointment(Adapalene Gel 0.1% 15Gm tube Wt: 495 Kgs (Net Cont: Adapal.0.50 Kgs, Edetate0.5Kgs, Carbomer 4.21Kgs, Methyl Par 0.50 Kgs, Poloxamer 0.99Kgs, Propylene 19.80kgs ,Tubes 33000Nos))	1 Number
(ii)	Medical cream and ointment(Adapalene Gel 0.1% 45 Gm tube Wt:11565 Kgs (Net Cont: Adapal.11.57 Kgs, Edetate11.57Kgs, Carbomer 98.30Kgs, Methyl Par 11.57 Kgs, Poloxamer 23.13Kgs, Propylene 462.60 kgs ,Tubes 257,000Nos))	1 Number

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

Note:

- a. **1.03 kg.** of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**
- b. **1.02 kg.** of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**
- c. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	208 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006134AM23
RA File Number	03AX04003729 AM23
Licence No and Date	0311021217/07/02/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Aug/202324/11 dated 22/08/2023** against advance authorization **No.0311007542 dated 07/10/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Isobornyl Cyclohexanol	1 kg.	1	Gum Turpentine Oil	1.582 kg.

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

Case No.	209 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006153AM23
RA File Number	34AX04001000 AM23
Licence No and Date	3411003357/07/02/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	210 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006165AM23
RA File Number	03AX04005445 AM23
Licence No and Date	0311021243/08/02/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	211 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006212AM23
RA File Number	34AX04001024 AM23
Licence No and Date	3411003367/09/02/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	212 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved

Party Name	SCOTT EDIL PHARMACIA LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024										
HQ File Number	HQRNORM APPLY 00006227AM23										
RA File Number	30AX04000504 AM23										
Licence No and Date	3011003137/10/02/2023										
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under. <table 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>Erythropoietin Injection 4000IU/ml (Each ml contains : Erythropoietin Concentrated Solution BP 4000 IU/ML) (net content of Recombinant Human Erythropoietin 4000IU/ML is not less than 28.571 litre)</td><td>1 Vial</td><td>1</td><td>Recombinant Human Erythropoietin 4000IU/ML (ready to fill bulk)</td><td>1.02 ml.</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.	Erythropoietin Injection 4000IU/ml (Each ml contains : Erythropoietin Concentrated Solution BP 4000 IU/ML) (net content of Recombinant Human Erythropoietin 4000IU/ML is not less than 28.571 litre)	1 Vial	1	Recombinant Human Erythropoietin 4000IU/ML (ready to fill bulk)	1.02 ml.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Erythropoietin Injection 4000IU/ml (Each ml contains : Erythropoietin Concentrated Solution BP 4000 IU/ML) (net content of Recombinant Human Erythropoietin 4000IU/ML is not less than 28.571 litre)	1 Vial	1	Recombinant Human Erythropoietin 4000IU/ML (ready to fill bulk)	1.02 ml.							

Case No.	213 / NC/3/MEET/Dec/202324/19										
Case Status	Case Approved										
Party Name	KOPRAN LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024										
HQ File Number	HQRNORM APPLY 00006260AM23										
RA File Number	03AX04005475 AM23										
Licence No and Date	0311021361/13/02/2023										
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Oct/202324/15 dated 13/10/2023 against advance authorization No. 0311004745 dated 19/06/2021, 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: <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>MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE)</td><td>1 kg.</td><td>1</td><td>MEROPENEM NON STERILE MEROPENEM TRIHYDRATE</td><td>0.8968 kg.</td></tr> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE)	1 kg.	1	MEROPENEM NON STERILE MEROPENEM TRIHYDRATE	0.8968 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE)	1 kg.	1	MEROPENEM NON STERILE MEROPENEM TRIHYDRATE	0.8968 kg.							

[Containing NLT 84% Sterile Meropenem]			NON STERILE	
		2	Packing Material	Relevant, as per Packing Policy

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

Case No.	214 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006267AM23
RA File Number	09AX04000893 AM23
Licence No and Date	0911004453/13/02/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	215 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SYNERGIA SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006312AM23
RA File Number	03AX04005369 AM23
Licence No and Date	0311021429/14/02/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	216 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006351AM23
RA File Number	03AX04005363 AM23
Licence No and Date	0311021477/16/02/2023

Norms Committee Decision:

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

Sl.No	Export Product	Quantity
(i)	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 5 Gm Tube Tot Wt: 450 Kgs (Net Cont: Beta 0.72Kgs, Ceto 32.40Kgs, Fusi 9.45 Kgs, Macro 8.10 Kgs, Tubes 90000 Nos))	1 Number
(ii)	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 15 Gm Tube Tot Wt: 4200 Kgs (Net Cont: Beta 5.60 Kgs, Ceto 302.40Kgs, Fusi 87.65Kgs, Macro 75.60 Kgs, Tubes 280000 Nos))	1 Number
(iii)	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 30 Gm Tube Tot Wt: 12960 Kgs (Net Cont: Beta 16.848Kgs, Ceto 933.12Kgs, Fusi 270.864Kgs, Macro 233.28Kgs, Tubes 432000 Nos))	1 Number
(iv)	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 60 Gm Tube Tot Wt: 8616 Kgs (Net Cont: Beta 10.916Kgs, Ceto 620.352Kgs, Fusi 179.385 Kgs, Macro 155.088 Kgs, Tubes 143600 35000 Nos))	1 Number
(v)	Medical Creams & Ointments(Fusidic Acid Cream 15 Gm Tube Tot Wt: 7200 Kgs (Net Cont: Fusi 150.34 Kgs, Tubes 480000 Nos))	1 Number
(vi)	Medical Creams &; Ointments(Fusidic Acid Cream 30 Gm Tube Tot Wt: 3600 Kgs (Net Cont: Fusi 75.03Kgs, Tubes 120000 Nos))	1 Number

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

Note:

- a. **1.03 kg.** of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**
- b. **1.02 kg.** of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**
- c. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	217 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	PUNJAB CHEMICALS AND CROP PROTECTION LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006398AM23
RA File Number	03AX04005601 AM23
Licence No and Date	0311021526/17/02/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRIMETHYL SULFOXONIUM BROMIDE	1 kg.	1	Dimethyl Sulfoxide	0.930 kg.
		2	Trimetyl Orthoformate	0.018 kg.

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

Case No.	218 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006402AM23

RA File Number	09AX04001018 AM23			
Licence No and Date	0911004488/17/02/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CAPRYLYL GLYCOL / SALICAP-G (Octane-1,2-diol)	1 kg.	1	1 OCTENE	0.91 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	219 / NC/3/MEET/Dec/202324/19													
Case Status	Case Approved													
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024													
HQ File Number	HQRNORM APPLY 00007000AM23													
RA File Number	NA													
Licence No and Date	0911004488/17/02/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>CAPRYLYL GLYCOL / SALICAP-G (Octane-1,2-diol)</td><td>1 kg.</td><td>1</td><td>1 OCTENE</td><td>0.91 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CAPRYLYL GLYCOL / SALICAP-G (Octane-1,2-diol)	1 kg.	1	1 OCTENE	0.91 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
CAPRYLYL GLYCOL / SALICAP-G (Octane-1,2-diol)	1 kg.	1	1 OCTENE	0.91 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	220 / NC/3/MEET/Dec/202324/19			
Case Status	Case Deferred			
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			

HQ File Number	HQRNORM APPLY 00006441AM23
RA File Number	03AX04005543 AM23
Licence No and Date	0311021564/20/02/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Firm vide their letter dated 10.01.2023 have changed export description and export quantity (leading to change in import also). 2. The firm may be advised to furnish copy of Amended Licence, with export and import quantity and relevant details with DML.	

Case No.	221 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006487AM23
RA File Number	09AX04001024 AM23
Licence No and Date	0911004510/21/02/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	222 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SAVA HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006536AM23
RA File Number	31AX04000353 AM23
Licence No and Date	3111002045/23/02/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Whether export item is Blue Tablet or Pink Tablet, please clarify. 2. Content of Folic Acid in the DML for second export item only.	

Case No.	223 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006594AM23
RA File Number	30AX04000547 AM23
Licence No and Date	3011003202/24/02/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	224 / NC/3/MEET/Dec/202324/19			
Case Status	Case Approved			
Party Name	KOPRAN LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024			
HQ File Number	HQRNORM APPLY 00006648AM23			
RA File Number	03AX04005729 AM23			
Licence No and Date	0311021772/27/02/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Oct/202324/15 dated 13/10/2023 against advance authorization No. 0311004745 dated 19/06/2021 , 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.
MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE) [Containing NLT 84% Sterile Meropenem]	1 kg.	1	MEROPENEM NON STERILE MEROPENEM TRIHYDRATE NON STERILE	0.8968 kg.
		2	Packing Material	Relevant, as per Packing Policy

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

Case No.	225 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	KOPRAN LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024																
HQ File Number	HQRNORM APPLY 00006649AM23																
RA File Number	03AX04005732 AM23																
Licence No and Date	0311021773/27/02/2023																
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Oct/202324/15 dated 13/10/2023 against advance authorization No. 0311004745 dated 19/06/2021, 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: <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"> MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE) [Containing NLT 84% Sterile Meropenem] </td> <td rowspan="2">1 kg.</td> <td>1</td> <td>MEROPENEM NON STERILE MEROPENEM TRIHYDRATE NON STERILE</td> <td>0.8968 kg.</td> </tr> <tr> <td>2</td> <td>Packing Material</td> <td>Relevant, as per Packing Policy</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.	MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE) [Containing NLT 84% Sterile Meropenem]	1 kg.	1	MEROPENEM NON STERILE MEROPENEM TRIHYDRATE NON STERILE	0.8968 kg.	2	Packing Material	Relevant, as per Packing Policy
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE) [Containing NLT 84% Sterile Meropenem]	1 kg.	1	MEROPENEM NON STERILE MEROPENEM TRIHYDRATE NON STERILE	0.8968 kg.													
		2	Packing Material	Relevant, as per Packing Policy													

Case No.	226 / NC/3/MEET/Dec/202324/19							
Case Status	Case Approved							
Party Name	ENCUBE ETHICALS PRIVATE LIMITED							
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024							
HQ File Number	HQRNORM APPLY 00006678AM23							
RA File Number	03AX04005502 AM23							
Licence No and Date	0311021802/01/03/2023							
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms for export to US only are as under:- <table border="1"> <thead> <tr> <th>Sl.No</th> <th>Export Product</th> <th>Quantity</th> </tr> </thead> <tbody> <tr> <td>(i)</td> <td>MEDICAL CREAM AND OINTMENT(BENZOYL PEROXIDE CLINDAMYCIN GEL 1-5% 25GM Jar Benzoyl Peroxide 20Gm & Clindamycin5GmTotwt1875Kgnetcont:HydBen124.95,Carb26.25,d-</td> <td>1 Number</td> </tr> </tbody> </table>			Sl.No	Export Product	Quantity	(i)	MEDICAL CREAM AND OINTMENT(BENZOYL PEROXIDE CLINDAMYCIN GEL 1-5% 25GM Jar Benzoyl Peroxide 20Gm & Clindamycin5GmTotwt1875Kgnetcont:HydBen124.95,Carb26.25,d-	1 Number
Sl.No	Export Product	Quantity						
(i)	MEDICAL CREAM AND OINTMENT(BENZOYL PEROXIDE CLINDAMYCIN GEL 1-5% 25GM Jar Benzoyl Peroxide 20Gm & Clindamycin5GmTotwt1875Kgnetcont:HydBen124.95,Carb26.25,d-	1 Number						

	lim7.5,docsod0.75,Sodhyd4.2,clind22.75,prop56.25,pho20.625,Sod hy0.457-KGs - Jar,Cap,Bottle,cap,spatula-75000 No each)	
(ii)	MEDICAL CREAM AND OINTMENT(BENZOYL PEROXIDE CLINDAMYCIN GEL 1-5% 50GM Jar Benzoyl Peroxide 40Gm & Clindamycin10 Gm TotWt6250 Kg(Netcont:Hyd Ben416.5,Carb87.5,d-lim 25,docsod2.5,Sodhyd14,clinda74.25,prop187.5,phosp68.75,Sodhyd1.525-KGsJar,Cap,Bottle,capspatula-125000Noseach)	1 Number
(iii)	MEDICAL CREAM AND OINTMENT(BENZOYL PEROXIDE CLINDAMYCIN GEL PUMP1-5% 35GM Benzoyl Peroxide 28Gm,Clindamycin 7GmTot Wt1250Kg Netcon:Hyd Ben83.3,Carb17.5,d- lim5, docsod0.5,Sodhyd2.8,clinda14.85,prop37.5,phosp13.75,Sodhyd0.3-KGsPumpengi,Jar,Cap,Bottle,cap,spatula-35714Noseach)	1 Number
(iv)	MEDICAL CREAM AND OINTMENT(BENZOYL PEROXIDE CLINDAMYCIN GEL PUMP1-5% 50GM-Benzoyl Peroxide40Gm,Clindamycin10GmTot Wt1250Kg Netcont:Hyd Ben83.3,Carb17.5,d-lim5, docsod0.5,Sodhyd2.8,clinda14.85,prop37.5,phos13.75,Sodhyd0.305-KGsPumpengi,Jar,Cap,Bottle,cap,spatula-25000Noseach)	1 Number

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

Note:

- a. **1.03 kg.** of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**
- b. **1.02 kg.** of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**
- c. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA

concerned for redemption.

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

Case No.	227 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	ANUH PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006763AM23
RA File Number	03AX04005850 AM23
Licence No and Date	0311021914/06/03/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	228 / NC/3/MEET/Dec/202324/19
Case Status	Case Deferred
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM APPLY 00006767AM23
RA File Number	07AX04001781 AM23
Licence No and Date	0711006639/06/03/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	229 / NC/3/MEET/Dec/202324/19
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 19 and 05/01/2024
HQ File Number	HQRNORM REVIW00007175AM24
RA File Number	09AX04000124 AM24
Licence No and Date	0911005029/15/05/2023
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Methocarbamol	1 Kg.	1	Guaifenesin	1.05 kg.
		2	Sodium Methoxide Powder	0.005 kg.
		3	Dimethyl Carbonate	0.500 kg.
		4	Ammonium Chloride	0.015 kg.
		5	Ammonia Gas	0.250 kg.
		6	Toluene	0.300 kg.
		7	Methanol	0.700 kg.
		8	Activated carbon	0.005 kg.

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