



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

Email Office : dgft@nic.in , Phone Office : 011-23062777

(DES - III SECTION)**MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Mar/202223/22**DATED:** 24/03/2023Please 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/Mar/202223/22 dated 24/03/2023 of Norms Committee - III for the year 2022-23 was held on 24/03/2023 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	AJAY KUMAR,Deputy Director	DGFT(HQ)
2	NAND Lal,Technical Consultant	DPIIT
3	SHAISH KUMAR,Technical Consultant	DGFT
4	DINESHNARAIN MATHUR,Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004181AM23
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:- - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity.	

Case No.	2 / NC/3/MEET/Mar/202223/22													
Case Status	Case Approved													
Party Name	GLAND PHARMA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023													
HQ File Number	HQRNORM REVIW00006334AM23													
RA File Number	092404000481 AM14													
Licence No and Date	0910058788/31/12/2013													
Norms Committee Decision:														
The Committee considered the request of firm for inclusion of Export Product No. 1, which was left over by NC while ratifying adhoc norms of subject Advance Authorization and after deliberation, it was decided to ratify adhoc norms for Export Product No. 1 as under:														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td rowspan="2">Adenosine Injection Prefilled Syringe 3 mg/ ml, 2ml in a PFS</td><td rowspan="2">1 Number</td><td>1</td><td>Adenosine</td><td>0.0066 grams</td></tr><tr><td>2</td><td>Barrel Syringes</td><td>Relevant as per</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	Adenosine Injection Prefilled Syringe 3 mg/ ml, 2ml in a PFS	1 Number	1	Adenosine	0.0066 grams	2	Barrel Syringes	Relevant as per
Export Product	Qty.	Sl. No.	Import Items	Qty.										
Adenosine Injection Prefilled Syringe 3 mg/ ml, 2ml in a PFS	1 Number	1	Adenosine	0.0066 grams										
		2	Barrel Syringes	Relevant as per										

		3	V-OVS 10.6 Tip Caps	packing policy
		4	Plunger Stoppers	
		5	Plunger Rods	
		6	Filters (Plastic)	Consumable on Net to Net basis.
		7	Tubing (Plastic)	
		8	Reference Standards	

Rest of the earlier Minutes will remain the same.

RA may take appropriate action as per the decision of Norms Committee.

Case No.	3 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006489AM23
RA File Number	092404000485 AM14
Licence No and Date	0910058787/31/12/2013

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Low molecular weight Heparin, Nadroparin Calcium Injection 2,850 anti - Xa IU/0.3ml PFS(IU)	1 Number	1	Nadroparin Calcium	26.125 mg
			2	Barrel Syringes	1.0534 Nos.
			3	Needle Shield	1.0451 Nos.
			4	Plunger Stoppers	1.1091 Nos.

			5	Plunger Rods	1.0294 Nos.
			6	Preventis	1.05 Nos.
			7	Anti Factor Xa Test Kits	Not admissible
			8	Anti Factor IIa Test Kits	Not admissible
			9	Analytical Columns	Not admissible
			10	Analytical Guard Columns	Not admissible
			11	Medical Grade Paper	0.9 gram
			12	Tubing	0.020 cms
			13	Anti Factor Xa	Not admissible
			14	Anti Factor IIa	Not admissible
			15	N.M.R. Standard	Not admissible
			16	Mol.Wt.Standard	Not admissible
2	Low molecular weight Heparin, Nadroparin Calcium Injection 5,700 anti - Xa IU/0.6ml PFS(IU)	1 Number	1	Nadroparin Calcium	52.25 mg
			2	Barrel Syringes	1.0534 Nos.
			3	Needle Shield	1.0451 Nos.
			4	Plunger Stoppers	1.1091 Nos.
			5	Plunger Rods	1.0294 Nos.
			6	Preventis	1.05 Nos.
			7	Anti Factor Xa Test Kits	Not admissible

			8	Anti Factor IIa Test Kits	Not admissible
			9	Analytical Columns	Not admissible
			10	Analytical Guard Columns	Not admissible
			11	Medical Grade Paper	0.9 gram
			12	Tubing	0.020 cms
			13	Anti Factor Xa	Not admissible
			14	Anti Factor IIa	Not admissible
			15	N.M.R. Standard	Not admissible
			16	Mol.Wt.Standard	Not admissible

Case No.	4 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006335AM23
RA File Number	092404000344 AM15
Licence No and Date	0910061096/15/10/2014

Norms Committee Decision:

The Committee considered the request of firm for inclusion of Export Product No. 1, which was left over by NC while ratifying adhoc norms of subject Advance Authorization and after deliberation, it was decided to ratify adhoc norms for Export Product No. 1 as under:

Export Product	Qty.	Sl. No.	Import Items	Qty.
Adenosine Injection Prefilled Syringe 3 mg/ ml, 2ml in a PFS	1 Number	1	Adenosine	0.0066 grams
		2	Barrel Syringes	Relevant as per

		3	V-OVS 10.6 Tip Caps	packing policy
		4	Plunger Stoppers	
		5	Plunger Rods	
		6	Filters (Plastic)	Consumable on Net to Net basis.
		7	Tubing (Plastic)	
		8	Reference Standards	

Rest of the earlier Minutes will remain the same.

RA may take appropriate action as per the decision of Norms Committee.

Case No.	5 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006348AM23
RA File Number	092404000709 AM15
Licence No and Date	0910062070/26/05/2015

Norms Committee Decision:

The Committee considered the request of firm for inclusion of Export Product No. 1, which was left over by NC while ratifying adhoc norms of subject Advance Authorization and after deliberation, it was decided to ratify adhoc norms for Export Product No. 1 as under:

Export Product	Qty.	Sl. No.	Import Items	Qty.
Enoxaparin PFS 20 mg	1 Number	1	Heparin Sodium Powder	0.0634 gm
		2	Barrel Syringes	1.1172 Nos.
		3	Needle Shield	1.164 Nos.

		4	Plunger Stoppers	1.1292 Nos.
		5	Plunger Rods	1.0279 Nos.
		6	Preventis Rubber	1.0361 Nos.

Rest of the earlier Minutes will remain the same.

RA may take appropriate action as per the decision of Norms Committee.

Case No.	6 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006350AM23
RA File Number	092404000712 AM15
Licence No and Date	0910062071/26/05/2015

Norms Committee Decision:

The Committee considered the request of firm for inclusion of Export Product No. 1, which was left over by NC while ratifying adhoc norms of subject Advance Authorization and after deliberation, it was decided to ratify adhoc norms for Export Product No. 1 as under:

Export Product	Qty.	Sl. No.	Import Items	Qty.
Enoxaparin PFS 20 mg	1 Number	1	Heparin Sodium Powder	0.0634 gm
		2	Barrel Syringes	1.1172 Nos.
		3	Needle Shield	1.164 Nos.
		4	Plunger Stoppers	1.1292 Nos.
		5	Plunger Rods	1.0279 Nos.
		6	Preventis Rubber	1.0361 Nos.

Rest of the earlier Minutes will remain the same.

RA may take appropriate action as per the decision of Norms Committee.

Case No.	7 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005997AM23
RA File Number	039404000859 AM16
Licence No and Date	0310802380/09/02/2016
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:- i. Copy of Shipping Bill indicating percentage purity of export product. ii. Copy of Bill of Entry indicating percentage purity of import product.	

Case No.	8 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006339AM23
RA File Number	092404000357 AM17
Licence No and Date	0910064221/30/09/2016
Norms Committee Decision:	
The Committee considered the request of firm for inclusion of Export Product No. 1, which was left over by NC while ratifying adhoc norms of subject Advance Authorization and after deliberation, it was decided to ratify adhoc norms for Export Product No. 1 as under:	

		3	V-OVS 10.6 Tip Caps	packing policy
		4	Plunger Stoppers	
		5	Plunger Rods	
		6	Filters (Plastic)	Consumable on Net to Net basis.
		7	Tubing (Plastic)	
		8	Reference Standards	

Rest of the earlier Minutes will remain the same.

RA may take appropriate action as per the decision of Norms Committee.

Case No.	9 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005839AM23
RA File Number	039404000733 AM18
Licence No and Date	0310817950/20/12/2017
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:-	
i. Copy of Shipping Bill indicating percentage purity of export product. ii. Copy of Bill of Entry indicating percentage purity of import product.	

Case No.	10 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	REYAANSH HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00004873AM23
RA File Number	039504000872 AM18
Licence No and Date	0310818545/16/01/2018

Norms Committee Decision:

Deferred for comments of TE.

Case No.	11 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005945AM23
RA File Number	039404000963 AM18
Licence No and Date	0310819402/23/02/2018

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and 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.
PAXIFLAS TRAMADOL HYDROCHLORIDE 37.5 mg AND PARACETAMOL 325mg ORODISPERSIBLE TABLETS	1 Number	1	PEARLITOL 50 C (35)	276.46 mg
		2	PEARLITOL 400 DC	276.46 mg

RA may take appropriate action as per the decision of Norms Committee.

Case No.	12 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	SIDDHARTH CARBOCHEM PRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00004691AM23
RA File Number	039504000992 AM18
Licence No and Date	0310819448/28/02/2018

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **1/82-ALC4/2019 dated 03.06.2019** against advance authorization No. **0310828654 dt. 26.04.2019**, 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.
METHYL SALICYLATE (MIN. 99%)	1 kg	1	METHANOL	1.1715 kg.

RA may take appropriate action as per the decision of Norms Committee.

Case No.	13 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005781AM23
RA File Number	039404000015 AM19
Licence No and Date	0310820585/23/04/2018

Norms Committee Decision:

Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:-

- i. Copy of Shipping Bill indicating percentage purity of export product.
- ii. Copy of Bill of Entry indicating percentage purity of import product.

Case No.	14 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	ARCH PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006595AM23
RA File Number	039404000142 AM19
Licence No and Date	0310822704/30/07/2018

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and 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.
3a-Hydroxy-7-keto-5b-cholan-24-oic acid (IP-5)	1 kg	1	Cholic Acid	1.32 kg
		2	Hydrazine Hydrate (80% solution)	1.403 kg

		3	Acetone	2.00 kg
		4	IEP OX 239 Spray Dried Enzyme Powder	0.0283 kg
		5	IEP OX 152 Spray Dried Enzyme Powder	0.050 kg
		6	IEP OX 243 Spray Dried Enzyme Powder	0.034 kg
		7	(B-NAD) B-Nicotinamide-adenine dinucleotide(Coenzyme-1)	0.0075 kg
RA may take appropriate action as per the decision of Norms Committee.				

Case No.	15 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	NATURAL REMEDIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00000342AM23
RA File Number	072404000170 AM19
Licence No and Date	0710113897/25/09/2018
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	16 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005229AM23
RA File Number	052404000392 AM19
Licence No and Date	0510408318/02/11/2018
Norms Committee Decision:	

The Committee considered the request of firm for review of adhoc 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.

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

Case No.	17 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005574AM23
RA File Number	039404000682 AM19
Licence No and Date	0310824972/12/11/2018

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and 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.
Enrofloxacin	1 kg	1	Ethyl 3- Cyclopropylamino-2-(2,4-Dichloro-5-Fluorobenzoyl)Acrylate	1.307 kg.
		2	N-Ethyl / Piperazine	0.490 kg.
		3	Methanol	0.334 kg.
		4	Caustic Soda Flakes	0.360 kg.

RA may take appropriate action as per the decision of Norms Committee.

Case No.	18 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	DINAKARA LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005704AM23
RA File Number	092404000571 AM19

Licence No and Date	0910067285/18/03/2019			
Norms Committee Decision:				
The Committee considered the request of firm for fixation of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. 6/82-ALC4/2019 dated 16.08.2019 against advance authorization No. 0910067692 dt. 25.06.2019, 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.
1-(2,4-Difluoro Phenyl)-2-(1H-1,2,4-triazole-1-yl) Ethanone (Ethanone Derivative)	1 kg	1	1,3-Difluoro Benzene	0.60 kg
RA may take appropriate action as per the decision of Norms Committee.				

Case No.	19 / NC/3/MEET/Mar/202223/22			
Case Status	Case Approved			
Party Name	HEMA DYECHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023			
HQ File Number	HQRNORM REVIW00001544AM23			
RA File Number	039404001141 AM19			
Licence No and Date	0310828400/16/04/2019			
Norms Committee Decision:				
The Committee considered the request of firm for review of adhoc norms and on the basis of information provided by the firm, it was decided to revise adhoc norms as under:				
Export product	Qty.	Sl. No.	Import items	Qty.
1,3 DIMETHOXY BENZENE/RESORCINOL DIMETHYL ETHER/M-DIMETHOXYBEZENE	1 kg	1	RESORCINOL/1,3DIHYDROXYBENZENE	1.19 kg
Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.				

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

Case No.	20 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	REYAANSH HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005643AM23
RA File Number	018205000836 AM20
Licence No and Date	0310832850/18/11/2019

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. (in grams)
1	IMPACT SOLUTION FOR CATS(0.40 ML EACH ML CONTAINS IMIDACLOPRID 100MG MOXIDECTIN 10 MG)	60000 Numbers	1	MOXIDECTIN	244.80
2	IMPACT SOLUTION FOR CATS ,(0.80ML EACH ML CONTAINS IMIDACLOPRID 100 MG MOXIDECTIN 10 MG)	60000 Numbers	2	MOXIDECTIN	489.60
3	IMPACT SOLUTION FOR DOGS(0.40 ML EACH ML CONTAINS IMIDACLOPRID 100MG MOXIDECTIN 25 MG)	60000 Numbers	3	MOXIDECTIN	612.00
4	IMPACT SOLUTION FOR DOGS(1ML EACH ML CONTAINS IMIDACLOPRID 100 MG MOXIDECTIN 25 MG)	38721 Numbers	4	MOXIDECTIN	987.38
5	IMPACT SOLUTION FOR DOGS(2.50 ML EACH ML CONTAINS IMIDACLOPRID 100MG MOXIDECTIN 25 MG)	60000 Numbers	5	MOXIDECTIN	3825.30
6	IMPACT SOLUTION FOR DOGS(4ML EACH ML CONTAINS IMIDACLOPRID 100MG MOXIDECTIN 25 MG)	9381 Numbers	6	MOXIDECTIN	956.86

RA may take appropriate action as per the decision of Norms Committee.

Case No.	21 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	REYAANSH HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005644AM23
RA File Number	018205000964 AM20
Licence No and Date	0310833938/06/01/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	22 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006630AM23
RA File Number	018205001104 AM20
Licence No and Date	0310835027/24/02/2020

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg
		2	Piperazine Anhydrous	0.390 kg

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

Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.

Case No.	23 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006631AM23
RA File Number	018205001105 AM20
Licence No and Date	0310835028/24/02/2020

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg
		2	Piperazine Anhydrous	0.390 kg

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

Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.

Case No.	24 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006632AM23
RA File Number	018205001106 AM20

Licence No and Date	0310835029/24/02/2020			
Norms Committee Decision:				
As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.				
The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:				
Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg
		2	Piperazine Anhydrous	0.390 kg
RA concerned may take further necessary action as per above decision of NC.				
Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.				

Case No.	25 / NC/3/MEET/Mar/202223/22		
Case Status	Case Approved		
Party Name	VEKO CARE PRIVATE LIMITED		
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023		
HQ File Number	HQRNORM REVIW00004314AM23		
RA File Number	318304000161 AM20		
Licence No and Date	3110067716/17/03/2020		
Norms Committee Decision:			
The Committee considered the request of firm for fixation of adhoc norms and 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:			
Sl. No.	Export product	Qty.	
1	Assurity plus Spot on Imidacloprid 10% w/v Moxidectin BP 1% w/v(0.4 ml x 6 pipettes (12 GM))	500 Numbers	

2	Assurity plus Spot on Imidacloprid 10% w/v Moxidectin BP 1% w/v(0.8 ml x 6 pipettes (58 GM))	1200 Numbers
3	Assurity plus Spot on Imidacloprid 10% w/v Moxidectin BP 2.5% w/v(1 ml x 6 pipettes (120 GM))	800 Numbers
4	Assurity plus Spot on Imidacloprid 10% w/v Moxidectin BP 2.5% w/v(2.5 ml x 6 pipettes (337.50 GM))	900 Numbers
5	Assurity plus Spot on Imidacloprid 10% w/v Moxidectin BP 2.5% w/v(4 ml x 6 pipettes (1410 GM))	2450 Numbers
6	Radicat Spot on Selamectin 6%(0.75 ml x 6 pipettes w/v(1890 GM))	5000 Numbers

Sl. No.	Import Items	Qty.
1	Moxidectin-EP	1993.132 gram
2	Selamectin-EP	1377.00 gram

RA may take appropriate action as per the decision of Norms Committee.

Case No.	26 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006633AM23
RA File Number	018205001156 AM20
Licence No and Date	0310835503/19/03/2020

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg
		2	Piperazine Anhydrous	0.390 kg

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

Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.

Case No.	27 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	RECKITT BENCKISER HEALTHCARE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00004127AM23
RA File Number	052404000025 AM21
Licence No and Date	0510414108/06/05/2020

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jul/202122/4 dated 15.07.2021** against advance authorization No. **0510409206 dt. 07.01.2019**, 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. for 1 number Lozenges
Cepacol Extra Strength Lozenges Cherry	1 Number Lozenges	1	ISOMALT ST-M	1913.10 mg
		2	LYCASIN 80/55 (MALTOTOL) (Water content 25%)	570.00 mg
		3	D&C red no. 33	0.055 mg

		4	FD&C Red no. 40	0.073 mg
		5	Benzocaine USP	15.30 mg
		6	Wild Cherry Flavour TAK 040489	12.71 mg
		7	Cherry Bark FL NAT TAK 054757	4.90 mg
		8	Intensate Cool Flavour TAK052848	4.70 mg

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

Case No.	28 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006634AM23
RA File Number	018205001376 AM21
Licence No and Date	0310836635/11/06/2020

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg
		2	Piperazine Anhydrous	0.390 kg

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

Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.

Case No.	29 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006635AM23
RA File Number	018205001440 AM21
Licence No and Date	0310836986/01/07/2020

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg
		2	Piperazine Anhydrous	0.390 kg

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

Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.

Case No.	30 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006636AM23
RA File Number	018205001441 AM21
Licence No and Date	0310836987/01/07/2020

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg
		2	Piperazine Anhydrous	0.390 kg

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

Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.

Case No.	31 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006637AM23
RA File Number	018205001442 AM21
Licence No and Date	0310836988/01/07/2020

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg
		2	Piperazine Anhydrous	0.390 kg
RA concerned may take further necessary action as per above decision of NC.				
Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.				

Case No.	32 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006638AM23
RA File Number	018205001443 AM21
Licence No and Date	0310836990/01/07/2020

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg
		2	Piperazine Anhydrous	0.390 kg

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

Note: The above norms are only for regularization purpose and no repeat licences will be issued on the

basis of these norms.

Case No.	33 / NC/3/MEET/Mar/202223/22													
Case Status	Case Approved													
Party Name	AARTI DRUGS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023													
HQ File Number	HQRNORM REVIW00006639AM23													
RA File Number	018205001444 AM21													
Licence No and Date	0310836991/01/07/2020													
Norms Committee Decision:														
As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.														
The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="2">Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)</td><td rowspan="2">1 kg</td><td>1</td><td>Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate</td><td>1.294 kg</td></tr><tr><td>2</td><td>Piperazine Anhydrous</td><td>0.390 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg	2	Piperazine Anhydrous	0.390 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg										
		2	Piperazine Anhydrous	0.390 kg										
RA concerned may take further necessary action as per above decision of NC.														
Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.														

Case No.	34 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006640AM23
RA File Number	018205001446 AM21
Licence No and Date	0310837001/01/07/2020
Norms Committee Decision:	

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg
		2	Piperazine Anhydrous	0.390 kg

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

Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.

Case No.	35 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006641AM23
RA File Number	018205001453 AM21
Licence No and Date	0310837056/07/07/2020

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-	1.294 kg

BP/EP/USP (Ciprofloxacin)		5Fluorobenzoyl) Acrylate	
	2	Piperazine Anhydrous	0.390 kg
RA concerned may take further necessary action as per above decision of NC.			
Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.			

Case No.	36 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	SHIVA BIO CHEM INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00004344AM23
RA File Number	502404000009 AM21
Licence No and Date	5010002703/07/08/2020
Norms Committee Decision:	
The Committee considered the request of firm for fixation of adhoc norms and it was observed that the firm still has not provided following information / documents, due to non-receipt of which, its case was earlier rejected too:	
i. COA of import item from foreign supplier indication percentage moisture content. ii. Complete specification of export item. iii. Process of manufacturing indicating wastage at each stage of manufacturing.	
Hence, it was decided to reject the case maintaining the status quo.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	37 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	SRI CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00002991AM23
RA File Number	042404000109 AM21
Licence No and Date	0410167147/07/10/2020

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to **reject** the case.

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

Case No.	38 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	018205001756AM21
RA File Number	039404000825 AM20
Licence No and Date	0310838959/16/10/2020

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and 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.
Enrofloxacin	1 kg	1	Ethyl 3- Cyclopropylamino-2-(2,4-Dichloro-5-Fluorobenzoyl)Acrylate	1.307 kg.
		2	N-Ethyl / Piperazine	0.490 kg.
		3	Methanol	0.334 kg.
		4	Caustic Soda Flakes	0.360 kg.

RA may take appropriate action as per the decision of Norms Committee.

Case No.	39 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00004724AM23
RA File Number	018205001755 AM21

Licence No and Date	0310838958/16/10/2020			
Norms Committee Decision:				
As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04.02.2023 under the Chairmanship of Shri Rajiv Kumar Soni, Jt. DGFT to ascertain the exact wastage of import items in their licences.				
The Committee examined the Factory Visit Report and after deliberation, it was decided to revise adhoc norms as under:				
Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg
		2	Piperazine Anhydrous	0.390 kg
RA concerned may take further necessary action as per above decision of NC.				
Note: The above norms are only for regularization purpose and no repeat licences will be issued on the basis of these norms.				

Case No.	40 / NC/3/MEET/Mar/202223/22			
Case Status	Case Approved			
Party Name	AARTI DRUGS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023			
HQ File Number	HQRNORM REVIW00005153AM23			
RA File Number	018205001788 AM21			
Licence No and Date	0310839173/28/10/2020			
Norms Committee Decision:				
The Committee considered the request of firm for fixation of adhoc norms and 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.
Norfloxacin	1 kg.	1	2,4 Dichloro-5-Fluoro Acetophenone(DCFA)	1.123 kg.

		2	Dimethyl Carbonate	1.01 kg.
		3	Dimethyl Formamide	0.50 kg.
		4	Mono Ethyl Amine(70%)	0.557 kg.
		5	Piperazine Anhydrous	0.665 kg.
		6	Methanol	1.20 kg.

RA may take appropriate action as per the decision of Norms Committee.

Case No.	41 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005154AM23
RA File Number	018205001818 AM21
Licence No and Date	0310839307/04/11/2020

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and 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.
Norfloxacin	1 kg.	1	2,4 Dichloro-5-Fluoro Acetophenone(DCFA)	1.123 kg.
		2	Dimethyl Carbonate	1.01 kg.
		3	Dimethyl Formamide	0.50 kg.
		4	Mono Ethyl Amine(70%)	0.557 kg.
		5	Piperazine Anhydrous	0.665 kg.

		6	Methanol	1.20 kg.
--	--	---	----------	----------

RA may take appropriate action as per the decision of Norms Committee.

Case No.	42 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00049028AM21
RA File Number	07AA04006399 AM21
Licence No and Date	0711000171/28/12/2020

Norms Committee Decision:

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

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

Case No.	43 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006413AM23
RA File Number	09AA04004807 AM21
Licence No and Date	0911000371/17/02/2021

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
AZATHIOPRINE 25 mg	1 Number	1	Azathioprine	25.00 mg
		2	Cellulose Microcrystalline	25.00 mg

		3	Mannitol	25.00 mg
		4	Corn Starch	7.00 mg
		5	Croscarmellose Sodium	2.75 mg
		6	Povidone K	4.00 mg
		7	Sodium Stearyl Fumarate	1.25 mg
		8	Hypromellose	1.15 mg
		9	Macrogol	0.20 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	44 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006416AM23
RA File Number	09AA04004799 AM21
Licence No and Date	0911000378/17/02/2021

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Methotrexate 2.5 mg	1 Number	1	Methotrexate	2.50 mg
		2	Anhydrous Calcium hydrogen phosphate	6.375 mg

		3	Lactose Monohydrate (Tabletose 80)	12.50 mg
		4	Sodium starch glycollate	1.80 mg
		5	Microcrystalline Cellulose	21.075 mg
		6	Purified Talc	0.375 mg
		7	Magnesium Stearate	0.375 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	45 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006420AM23
RA File Number	09AA04004798 AM21
Licence No and Date	0911000395/20/02/2021

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
HYDROXYUREA CAPSULES 500 mg	1 Number	1	Hydroxyurea USP	500.00 mg
		2	Colloidal Silicon Dioxide NF	1.50 mg
		3	Magnesium Stearate	0.50 mg
		4	Capsule size1	Relevant as per packing policy

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

Case No.	46 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006473AM23
RA File Number	09AA04005468 AM21
Licence No and Date	0911000463/05/03/2021

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Tamoxifen citrate 20 mg	1 Number	1	Tamoxifen citrate	30.40 mg
		2	Calcium hydrogen phosphate dihydrate	281.60 mg
		3	Povidone K 25	8.00 mg
		4	Sodium starch glycolate	20.00 mg
		5	magnesium stearate	5.00 mg
		6	Cellulose	33.00 mg
		7	Silica, colloidal anhydrous	2.00 mg

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

Case No.	47 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected

Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00109027AM21
RA File Number	03AA04031482 AM21
Licence No and Date	0311002729/22/03/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	48 / NC/3/MEET/Mar/202223/22																			
Case Status	Case Approved																			
Party Name	AARTI DRUGS LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023																			
HQ File Number	HQRNORM APPLY 00104785AM22																			
RA File Number	039404000639 AM21																			
Licence No and Date	0311002735/01/06/2021																			
Norms Committee Decision:																				
The Committee considered the request of firm for fixation of adhoc norms and 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:																				
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="4">Enrofloxacin</td><td rowspan="4">1 kg</td><td>1</td><td>Ethyl 3- Cyclopropylamino-2-(2,4-Dichloro-5-Fluorobenzoyl)Acrylate</td><td>1.307 kg.</td></tr><tr><td>2</td><td>N-Ethyl / Piperazine</td><td>0.490 kg.</td></tr><tr><td>3</td><td>Methanol</td><td>0.334 kg.</td></tr><tr><td>4</td><td>Caustic Soda Flakes</td><td>0.360 kg.</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Enrofloxacin	1 kg	1	Ethyl 3- Cyclopropylamino-2-(2,4-Dichloro-5-Fluorobenzoyl)Acrylate	1.307 kg.	2	N-Ethyl / Piperazine	0.490 kg.	3	Methanol	0.334 kg.	4	Caustic Soda Flakes	0.360 kg.
Export product	Qty.	Sl. No.	Import items	Qty.																
Enrofloxacin	1 kg	1	Ethyl 3- Cyclopropylamino-2-(2,4-Dichloro-5-Fluorobenzoyl)Acrylate	1.307 kg.																
		2	N-Ethyl / Piperazine	0.490 kg.																
		3	Methanol	0.334 kg.																
		4	Caustic Soda Flakes	0.360 kg.																
RA may take appropriate action as per the decision of Norms Committee.																				

Case No.	49 / NC/3/MEET/Mar/202223/22
----------	------------------------------

Case Status	Case Rejected
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00003402AM23
RA File Number	08AA04005392 AM22
Licence No and Date	0811001628/01/06/2021
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	50 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	ANTILA LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00165364AM22
RA File Number	08AA04018980 AM22
Licence No and Date	0811002348/18/08/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	51 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005815AM23
RA File Number	03AA040106163 AM22
Licence No and Date	0311007214/25/09/2021
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 following information / documents from the firm:	

“The firm may be advised to get their license amended for the export description as given in their Drug Manufacturing License and Batch Manufacturing Record.”

Case No.	52 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00195497AM22
RA File Number	03AA040105795 AM22
Licence No and Date	0311007265/27/09/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and decided to visit factory as there are large number of other similar cases of the company pending for ratification. Hence, the Committee decided to defer the case.	

Case No.	53 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005837AM23
RA File Number	03AA040106642 AM22
Licence No and Date	0311007268/28/09/2021
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 following information / documents from the firm:	
“The firm may be advised to get their license amended for the export description as given in their Drug Manufacturing License and Batch Manufacturing Record.”	

Case No.	54 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00002321AM23
RA File Number	03AA040118606 AM22
Licence No and Date	0311008613/16/11/2021
Norms Committee Decision:	

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

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

Case No.	55 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00303629AM22
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 it was observed that the firm still has not furnished its reply. Hence, the Committee decided to **reject** the case.

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

Case No.	56 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	SCITECH SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00311328AM22
RA File Number	03AA040131440 AM22
Licence No and Date	0311010245/07/01/2022

Norms Committee Decision:

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

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

Case No.	57 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	PORUS LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023

HQ File Number	HQRNORM APPLY 00315693AM22
RA File Number	09AX04000098 AM22
Licence No and Date	0911002275/12/01/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	58 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00318349AM22
RA File Number	31AX04000040 AM22
Licence No and Date	3111000876/14/01/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	59 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00321040AM22
RA File Number	03AX04000043 AM22
Licence No and Date	0311010585/17/01/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	60 / NC/3/MEET/Mar/202223/22										
Case Status	Case Approved										
Party Name	SWATI MENTHOL AND ALLIED CHEMICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023										
HQ File Number	HQRNORM APPLY 00321275AM22										
RA File Number	05AX04000573 AM22										
Licence No and Date	0511007997/17/01/2022										
Norms Committee Decision: . The Committee considered the case as per agenda and as per the process given by the firm, it was observed that there is no blending of any other item involved, hence, the case was examined only after taking distillation process to ascertain purity of 99.5% - 99.7% from 99%. Accordingly, 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: <table border="1"> <thead> <tr> <th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> <tr> <td>1,8 Cineole 99.5% - 99.7%</td><td>1 kg</td><td>1</td><td>Eucalyptol (Containing 1,8 Cineole 99%)</td><td>1.01 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.	1,8 Cineole 99.5% - 99.7%	1 kg	1	Eucalyptol (Containing 1,8 Cineole 99%)	1.01 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
1,8 Cineole 99.5% - 99.7%	1 kg	1	Eucalyptol (Containing 1,8 Cineole 99%)	1.01 kg							

Case No.	61 / NC/3/MEET/Mar/202223/22					
Case Status	Case Approved					
Party Name	AARTI DRUGS LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023					
HQ File Number	HQRNORM REVIW00005155AM23					
RA File Number	03AA04044735 AM22					
Licence No and Date	0311010626/18/01/2022					
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and 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: <table border="1"> <thead> <tr> <th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> </tbody> </table>		Export product	Qty.	Sl. No.	Import items	Qty.
Export product	Qty.	Sl. No.	Import items	Qty.		

Norfloxacin	1 kg.	1	2,4 Dichloro-5-Fluoro Acetophenone(DCFA)	1.123 kg.
		2	Dimethyl Carbonate	1.01 kg.
		3	Dimethyl Formamide	0.50 kg.
		4	Mono Ethyl Amine(70%)	0.557 kg.
		5	Piperazine Anhydrous	0.665 kg.
		6	Methanol	1.20 kg.

RA may take appropriate action as per the decision of Norms Committee.

Case No.	62 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00005521AM23
RA File Number	03AX04000818 AM22
Licence No and Date	0311010921/27/01/2022

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and as per the justification provided by the firm, it was observed that there is other compound present in the import and also yield is low because of 10% residue remaining, hence it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Dimethyl-2-methyl glutarate	1 kg	1	2-methyl glutaronitrile (Purity 86-87%)	0.85 kg

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

Case No.	63 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected

Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	NORM APPLY 00343126AM22
RA File Number	31AX04000059 AM22
Licence No and Date	3111000968/04/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	64 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00359473AM22
RA File Number	03AX04001229 AM22
Licence No and Date	0311011469/18/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and decided to visit factory as there are large number of other similar cases of the company pending for ratification. Hence, the Committee decided to defer the case.	

Case No.	65 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	GUPTA AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00381776AM22
RA File Number	05AX04001230 AM22
Licence No and Date	0511010862/10/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	66 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	AASHA BIOCHEM
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00383526AM22
RA File Number	10AX04000077 AM22
Licence No and Date	1011000943/11/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	67 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	GUPTA AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00386306AM22
RA File Number	05AX04001267 AM22
Licence No and Date	0511010970/14/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	68 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	PROEC ENERGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00386396AM22
RA File Number	05AX04001262 AM22
Licence No and Date	0511010975/14/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence,	

the Committee decided to **reject** the case.

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

Case No.	69 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	DPB ANTIBIOTICS
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00387310AM22
RA File Number	03AX04001617 AM22
Licence No and Date	0311012908/15/03/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	70 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00409264AM22
RA File Number	03AX04002067 AM22
Licence No and Date	0311013503/31/03/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	71 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00409265AM22

RA File Number	03AX04002070 AM22
Licence No and Date	0311013504/31/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	72 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00409266AM22
RA File Number	03AX04002071 AM22
Licence No and Date	0311013505/31/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	73 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006096AM23
RA File Number	03AX04000111 AM23
Licence No and Date	0311013749/10/04/2022
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Dec/202223/17 dated 13/01/2023 against advance authorization No. 0311004509 dt. 10/06/2021, 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.
DI-NONYLATED DIPHENYLAMINE (YALUB DND)	1 kg	1	DIPHENYLAMINE	0.4134 kg
		2	NONENE	0.800 kg
		3	ACTIVATED CLAY	0.05 kg

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

Case No.	74 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006097AM23
RA File Number	03AX04000094 AM23
Licence No and Date	0311013750/10/04/2022

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202223/17 dated 13/01/2023** against advance authorization No. **0311004509 dt. 10/06/2021**, 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.
DI-NONYLATED DIPHENYLAMINE (YALUB DND)	1 kg	1	DIPHENYLAMINE	0.4134 kg
		2	NONENE	0.800 kg
		3	ACTIVATED CLAY	0.05 kg

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

Case No.	75 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM REVIW00006099AM23
RA File Number	03AX04000163 AM23
Licence No and Date	0311013879/17/04/2022

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202223/17 dated 13/01/2023** against advance authorization No. **0311004509 dt. 10/06/2021**, 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.
DI-NONYLATED DIPHENYLAMINE (YALUB DND)	1 kg	1	DIPHENYLAMINE	0.4134 kg
		2	NONENE	0.800 kg
		3	ACTIVATED CLAY	0.05 kg

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

Case No.	76 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	AVID ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00000351AM23
RA File Number	34AX04000065 AM23
Licence No and Date	3411002146/20/04/2022

Norms Committee Decision:

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

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

Case No.	77 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00000535AM23
RA File Number	31AX04000023 AM23
Licence No and Date	3111001324/02/05/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
TYLODOX GOLD Powder (Pack size 1 Kgs Jar)(Each gram powder contains: Tylosin Tartrate BP (Vet) equivalent to Tylosin base 100 mg Doxycycline Hyclate BP Equivalent to Doxycycline 200 mg)	1 number	1	Tylosin Tartrate EP	0.101 kg.
		3	Doxycycline Hyclate BP/EP/USP	0.202 kg.
TYLODOX GOLD Powder (Pack size 100 Gms sachet)(Each gram powder contains: Tylosin Tartrate BP (Vet) equivalent to Tylosin base 100 mg Doxycycline Hyclate BP Equivalent to Doxycycline 200 mg)	1 number	2	Tylosin Tartrate EP	10.1 gm.
		4	Doxycycline Hyclate BP/EP/USP	20.2 gm
GENTADOX GOLD Powder (pack Size 1 Kgs Jar)(Each gram powder contains: Doxycycline Hyclate 200mg, Gentamycin Sulphate 100mg)	1 number	5	Doxycycline Hyclate BP/EP/USP	0.202 kg
GENTADOX GOLD Powder (pack Size 100 Gms Sachet)(Each gram powder contains: Doxycycline Hyclate 200mg, Gentamycin Sulphate 100mg)	1 number	6	Doxycycline Hyclate BP/EP/USP	20.2 gm
NEODOX -GOLD Powder (pack Size 1 Kgs Jar)(Each gram powder contains: Each gram powder contains: Doxycycline Hyclate BP Equivalent to Doxycycline 100 mg Neomycin Sulfate BP 100 mg)	1 number	7	Doxycycline Hyclate BP/EP/USP	0.101 kg.
NEODOX -GOLD Powder (pack Size 100 Gms Sachet)(Each gram powder contains: Doxycycline Hyclate BP Equivalent to Doxycycline 100 mg Neomycin Sulfate BP 100 mg)	1 number	8	Doxycycline Hyclate BP/EP/USP	10.1 gm

AmitraXX 12.5% EC / Amitraz 12.5% EC (pack Size 1 Litre Bottle), Each ml contains Amitraz IP/BP 12.5%	1 number	9	Amitraz IP/BP	12.75 gm
AmitraXX 12.5% EC / Amitraz 12.5% EC (pack Size 100 ml Bottle), Each ml contains Amitraz IP/ BP 12.5%	1 number	10	Amitraz IP/BP	1.275 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	78 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00000730AM23
RA File Number	03AX04000676 AM23
Licence No and Date	0311014666/12/05/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	79 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00000801AM23
RA File Number	03AX04000672 AM23
Licence No and Date	0311014751/17/05/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	80 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected

Party Name	KOSHA CHEMTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00000806AM23
RA File Number	03AX04000276 AM23
Licence No and Date	0311014758/17/05/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	81 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	ALG CHEMICALS.
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00000883AM23
RA File Number	03AX04000006 AM23
Licence No and Date	0311014857/19/05/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC	

Case No.	82 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	ASSOCIATED DYESTUFF PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00000991AM23
RA File Number	08AX04000268 AM23
Licence No and Date	0811005014/25/05/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case.	

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

Case No.	83 / NC/3/MEET/Mar/202223/22
Case Status	Case Rejected
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00001004AM23
RA File Number	05AX04000553 AM23
Licence No and Date	0511012820/26/05/2022

Norms Committee Decision:

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

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

Case No.	84 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00001418AM23
RA File Number	03AX04000671 AM23
Licence No and Date	0311014746/16/06/2022

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and 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.
Enrofloxacin	1 kg	1	Ethyl 3- Cyclopropylamino-2-(2,4-Dichloro-5-Fluorobenzoyl)Acrylate	1.307 kg.
		2	N-Ethyl / Piperazine	0.490 kg.
		3	Methanol	0.334 kg.

		4	Caustic Soda Flakes	0.360 kg.
--	--	---	---------------------	-----------

RA may take appropriate action as per the decision of Norms Committee

Case No.	85 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003617AM23
RA File Number	03AX04003479 AM23
Licence No and Date	0311018489/11/10/2022
Norms Committee Decision:	
Deferred for comments of TE	

Case No.	86 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	LIVEALTH BIOPHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003619AM23
RA File Number	03AX04003335 AM23
Licence No and Date	0311018491/11/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	87 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	BIODEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003620AM23
RA File Number	05AX04001975 AM23
Licence No and Date	0511015214/11/10/2022
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/Jan/202223/18 dated 23/01/2023 against advance authorization No. 0511014609 dated 02/09/2022 , 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.
NASAL SPRAY(SNAP-ON, S20 WHITE SMOOTH, NASAL ADAPTOR WITH GLASS BOTTLE & CHEMICALS)	99000 Numbers	1	NASAL ADAPTOR FOR MFG OF NASAL SPRAY	Relevant, on Net to Net basis with accountability
		2	GLASS BOTTLE FOR MFG. OF NASAL SPRAY	Relevant, on Net to Net basis with accountability

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

Case No.	88 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003623AM23
RA File Number	34AX04000660 AM23
Licence No and Date	3411002878/11/10/2022

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/Jan/202223/18 dated 23/01/2023** against advance authorization No. **3411002686 dated 26/08/2022**, 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.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	89 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred

Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003624AM23
RA File Number	04AX04000581 AM23
Licence No and Date	0411004084/11/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	90 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003625AM23
RA File Number	04AX04000582 AM23
Licence No and Date	0411004085/11/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	91 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003629AM23
RA File Number	34AX04000662 AM23
Licence No and Date	3411002884/11/10/2022
Norms Committee Decision:	
Deferred for comments of TE	

Case No.	92 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003632AM23
RA File Number	34AX04000320 AM23
Licence No and Date	3411002888/11/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and after going through the description of Export Product, it was observed that it comes under Food Category, which is dealt by Norms Committee - 6.

Hence, it was decided to transfer the case to Norms Committee-6.

Case No.	93 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	ENVEE DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003636AM23
RA File Number	34AX04000425 AM23
Licence No and Date	3411002892/11/10/2022

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. **0311016564 dated 25/07/2022**, 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.
DEXAMETHASONE SODIUM PHOSPHATE (BP/USP)	1 kg	1	DEXAMETHASONE	0.78 kg

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

Case No.	94 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003639AM23
RA File Number	34AX04000654 AM23
Licence No and Date	3411002894/11/10/2022
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/Jan/202223/18 dated 23/01/2023** against advance authorization No. **3411002728 dated 02/09/2022**, 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Duloxetine Caps.20 mg(Duloxetine Caps.20 mg Capsule (Net content of active ingredients 54.000 kgs))	1 Number	1	Duloxetine Hydrochloride Ph,Eur.	22.88 mg
			2	Sugar Spheres (30-35 PHARM-A-SPHERES)	20.33 mg
			3	Hypromellose (Pharmacoat 606)	20.00 mg
			4	Talc (Luzenac Pharma Ultra Micronised grade)	12.63 mg
			5	Sucrose (Compressuc PS)	15.67 mg
			6	Hypromellose Phthalate (HP 55)	12.07 mg
			7	Triethyl Citrate	1.21 mg
2	Duloxetine Caps. 30 mg(Duloxetine Caps. 30 mg Capsule (Net content of active ingredients 210.00 kgs))	1 Number	1	Duloxetine Hydrochloride Ph,Eur.	34.36 mg
			2	Sugar Spheres (30-35 PHARM-A-SPHERES)	30.50 mg
			3	Hypromellose (Pharmacoat 606)	30.00 mg
			4	Talc (Luzenac Pharma Ultra Micronised grade)	18.94 mg
			5	Sucrose (Compressuc PS)	23.50 mg
			6	Hypromellose Phthalate (HP 55)	18.10 mg
			7	Triethyl Citrate	1.81 mg

3	Duloxetine Caps. 40 mg(Duloxetine Caps. 40 mg (Net content of active ingredients 120.000 kgs))	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	45.76 mg
			2	Sugar Spheres (30-35 PHARM-A-SPHERES)	40.67 mg
			3	Hypromellose (Pharmacoat 606)	40.00 mg
			4	Talc (Luzenac Pharma Ultra Micronised grade)	25.26 mg
			5	Sucrose (Compressuc PS)	31.34 mg
			6	Hypromellose Phthalate (HP 55)	24.14 mg
			7	Triethyl Citrate	2.41 mg
4	Duloxetine Caps. 60 mg(Duloxetine Caps. 60 mg (Net content of active ingredients 450.00 kgs))	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	68.71 mg
			2	Sugar Spheres (30-35 PHARM-A-SPHERES)	61.00 mg
			3	Hypromellose (Pharmacoat 606)	60.00 mg
			4	Talc (Luzenac Pharma Ultra Micronised grade)	37.88 mg
			5	Sucrose (Compressuc PS)	47.00 mg
			6	Hypromellose Phthalate (HP 55)	36.20 mg
			7	Triethyl Citrate	3.62 mg

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

Case No.	95 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003643AM23

RA File Number	09AX04000594 AM23
Licence No and Date	0911003780/11/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	96 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003644AM23
RA File Number	05AX04001966 AM23
Licence No and Date	0511015238/11/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Export Item Name: Amoxycillin Trihydrate and Clavulanate Potassium + Silicon Dioxide (1:1) Suspension 156.25mg/5ml((100ml Bottle, Each 5 ml contains Amoxycillin Trihydrate equivalent to Amoxycillin 125mg & Clavulanate Potassium + Silicon Dioxide (1:1) equivalent to Clavulanic acid 31.25mg) (Equivalent to 112.500Kg of Amoxycillin Trihydrate & 28.125Kg of Clavulanate)	1 Number	1	Amoxycillin Trihydrate	2625.00 mg.
			2	Clavulanate Potassium + Silicon Dioxide (1:1)	1550.65 mg.
2	Amoxycillin Trihydrate and Clavulanate Potassium + Silicon Dioxide (1:1) Suspension 228.50mg/5ml((70ml Bottle, Each 5 ml contains Amoxycillin Trihydrate equivalent to Amoxycillin 200mg & Clavulanate Potassium + Silicon Dioxide (1:1) equivalent to Clavulanic acid 28.5mg) (Equivalent to 98.000Kg of Amoxycillin Trihydrate & 13.965Kg of Clavulanate)	1 Number	3	Amoxycillin Trihydrate	2940 mg.
			4	Clavulanate Potassium + Silicon Dioxide (1:1)	989.935 mg.
3	Amoxycillin Trihydrate and Clavulanate Potassium + Silicon Dioxide (1:1) Suspension 312.5mg/5ml((60ml Bottle, Each 5 ml contains Amoxycillin Trihydrate equivalent to Amoxycillin 250mg & Clavulanate Potassium + Silicon Dioxide (1:1) equivalent to Clavulanic acid 62.5mg) (Equivalent to 105.000Kg of Amoxycillin Trihydrate & 26.250Kg of Clavulanate)	1 Number	5	Amoxycillin Trihydrate	3150.00 mg.
			6	Clavulanate Potassium + Silicon Dioxide (1:1)	1860.078 mg.

4	Amoxycillin Trihydrate and Clavulanate Potassium + Silicon Dioxide (1:1) Suspension 457.00mg/5ml((70ml Bottle, Each 5 ml contains Amoxycillin Trihydrate equivalent to Amoxycillin 400mg & Clavulanate Potassium + Silicon Dioxide (1:1) equivalent to Clavulanic acid 57mg) (Equivalent to 196.000Kg of Amoxycillin Trihydrate & 27.930Kg of Clavulanate)	1 Number	7	Amoxycillin Trihydrate	5880.00 mg.
			8	Clavulanate Potassium + Silicon Dioxide (1:1)	1979.87 mg.

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

Case No.	97 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003648AM23
RA File Number	05AX04001858 AM23
Licence No and Date	0511015244/11/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	98 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003663AM23
RA File Number	09AX04000574 AM23
Licence No and Date	0911003782/12/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	99 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	SMILAX LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003666AM23
RA File Number	09AX04000263 AM22
Licence No and	0911003783/12/10/2022

Date				
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. 0911001113 dated 24/06/2021, 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.
CLOPIDOGREL CAMPHORSULFONATE	1 kg	1	Thiophene-2-Ethylamine	0.53 kg
		2	L-Camphor Sulfonic Acid	0.455 kg
		3	Isopropyl Acetate	1.82 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	100 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003691AM23
RA File Number	09AX04000567 AM23
Licence No and Date	0911003791/13/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	101 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	VINS BIOPRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003701AM23
RA File Number	09AX04000630 AM23
Licence No and Date	0911003795/13/10/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and it was decided to refer the case to Department of Bio Technology (DBT) for obtaining their comments.

Case No.	102 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003702AM23
RA File Number	34AX04000674 AM23
Licence No and Date	3411002906/13/10/2022

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/Jan/202223/18 dated 23/01/2023** against advance authorization No. **3411002686 dated 26/08/2022**, 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.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	103 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003705AM23
RA File Number	03AX04003633 AM23
Licence No and Date	0311018563/14/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to ratify adhoc norms as per **SION A-412**.

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

Case No.	104 / NC/3/MEET/Mar/202223/22
----------	-------------------------------

Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003712AM23
RA File Number	09AX04000518 AM23
Licence No and Date	0911003801/14/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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. (in Kg.)
Piperacillin USP/Ph.Eur/BP(Piperacillin Monohydrate)	1 kg.	1	6-Amino Penicillanic Acid (6-APA)	0.5139
		2	4-Ethyl-2, 3 Dioxo Piperazine (EDP)	0.4113
		3	Triethylamine	0.577
		4	Trimethyl Chlorosilane	0.3778
		5	Triphosgene	0.3154
		6	Pivaloyl Chloride	0.3058
		7	Carbon Enoanticromos (Activated carbon)	0.063
		8	D(-) Alpha Phenyl Glycine Base	0.4015
		9	Potassium Carbonate (Anhydrous)	0.1838
		10	Methanol (Methyl Alcohol)	0.2778
		11	Methylene Chloride	2.810
		12	Isopropyl Alcohol	0.320

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

Case No.	105 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003713AM23
RA File Number	09AX04000603 AM23
Licence No and Date	0911003803/14/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	106 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	RUMIT LIFE CARE
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003723AM23
RA File Number	03AX04003613 AM23
Licence No and Date	0311018575/14/10/2022

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/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0311013605 dated 04/04/2022**, 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.
Betamethasone Dipropionate IP/BP/EP/USP	1 kg	1	Betamethasone IP/BP/EP/USP	0.868 kg

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

Case No.	107 / NC/3/MEET/Mar/202223/22
----------	-------------------------------

Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003742AM23
RA File Number	05AX04001751 AM23
Licence No and Date	0511015334/14/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	108 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003759AM23
RA File Number	03AX04003669 AM23
Licence No and Date	0311018602/16/10/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:	
i. Function of Acetaldoxime in chemical reaction. ii. Percentage yield at every stage of reaction. iii. Justification for low yield of 44%. iv. Commercial value of By-Product High Boiler v. Production Consumption data for last year duly certified by GST.	

Case No.	109 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ORIENTAL AROMATICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003761AM23
RA File Number	03AX04003660 AM23
Licence No and Date	0311018607/17/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	110 / NC/3/MEET/Mar/202223/22
----------	-------------------------------

Case Status	Case Approved
Party Name	SANOFI INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003762AM23
RA File Number	03AX04003648 AM23
Licence No and Date	0311018608/17/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
EPILIM CR 200MG TABS 100'S(EPILIM CR SODIUM VALPROATE- 133.2 & VALPROIC ACID-58MG TAB CR)((Total net content of Sodium Valproate 4129.20 Kgs & Valproic Acid 1798 Kgs))	1 number	1	Sodium Valproate	135.864 mg.
		2	Valproic Acid	59.16 mg.
EPILIM CR 300MG TABS 100'S(EPILIM CR SODIUM VALPROATE- 199.8 & VALPROIC ACID-87MG TAB CR)((Total net content of Sodium Valproate 9990 Kgs & Valproic Acid 4350 Kgs))	1 number	3	Sodium Valproate	203.796 mg.
		4	Valproic Acid	88.74 mg.
EPILIM CR 500MG TABS 100'S(EPILIM CR SODIUM VALPROATE- 333 & VALPROIC ACID- 145MG TAB CR)((Total net content of Sodium Valproate 16650 Kgs & Valproic Acid 7250 Kgs))	1 number	5	Sodium Valproate	339.66 mg.
		6	Valproic Acid	147.90 mg.

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

Case No.	111 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003765AM23
RA File Number	08AX04001180 AM23
Licence No and Date	0811006263/17/10/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and 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.
DOXEPIN HYDROCHLORIDE CREAM 5% , 45G TUBE US (EACH TUBE CONTAINS : DOXEPIN HYDROCHLORIDE CREAM 5%)(EACH CONTAINS: DOXEPIN HYDROCHLORIDE, USP, 5% (EQUIVALENT TO 4.4% DOXEPIN) NET CONTENT OF DOXEPIN BP SHOULD NOT BE LESS THAN 100.035 KGS. IN EXPORT ITEM)	1 Number	1	DOXEPIN HYDROCHLORIDE USP	2.295 gm.

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

Case No.	112 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003767AM23
RA File Number	03AX04003664 AM23
Licence No and Date	0311018619/17/10/2022

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/202122/10 dated 12/11/2021** against advance authorization No. **0311000293 dated 22-12-2020**, 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.
Loxoptic Ophthalmic Solution 5mg/ml((Each vial contains 5mg of Betaxolol Hydrochloride Net Wt of bulk drug is 4.50 kgs))	1 Vial	1	Betaxolol Hydrochloride	28.56 mg

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

Case No.	113 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003781AM23
RA File Number	09AX04000392 AM23
Licence No and Date	0911003808/17/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
GCLE(7-PHENYLACETAMIDEO-3-CHLOROMETHYL CEPHALOSPORANIC ACID PARA METHOXY BENZYL ESTER) (WHITE CRYSTALLINE)	1 Kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg.
		2	ACETONE	1.971 kg.
		4	METHYLENE CHLORIDE MC	3.29 kg.
		5	2 MERCAPTO BENZO THIAZOLE MBT	0.511 kg.
		6	METHANOL	1.971 kg.

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

Case No.	114 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023

and Date	
HQ File Number	HQRNORM APPLY 00003783AM23
RA File Number	03AX04003611 AM23
Licence No and Date	0311018641/17/10/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/justification from the firm: Firm has applied norms for (i) Phytosterol Natural Refined Phytosterol 95% and (ii) Natural Mixed Tocopherol 70%, separately. Whereas, export item No.2 is the Byproduct of export item no. 1. In view of above, no norms can be fixed in its present form.	

Case No.	115 / NC/3/MEET/Mar/202223/22				
Case Status	Case Approved				
Party Name	ALEMBIC PHARMACEUTICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023				
HQ File Number	HQRNORM APPLY 00003787AM23				
RA File Number	34AX04000683 AM23				
Licence No and Date	3411002918/17/10/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. (in grams)
1	Diclofenac Sodium Topical Solution 2 % 112 gm(Diclofenac Sodium Topical Solution 2 % 112 gm)	1 number	1	Diclofenac Sodium USP	2.2838
2	Diclofenac Sodium Topical Gel 3 % 100 gm (Diclofenac Sodium Topical Gel 3 % 100 gm)	1 number	2	Diclofenac Sodium USP	3.06

Case No.	116 / NC/3/MEET/Mar/202223/22				
Case Status	Case Approved				
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023				
HQ File Number	HQRNORM APPLY 00003788AM23				
RA File Number	09AX04000393 AM23				

Licence No and Date	0911003815/17/10/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and 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.
GCLE(7-PHENYLACETAMIDEO-3-CHLOROMETHYL CEPHALOSPORANIC ACID PARA METHOXY BENZYL ESTER) (WHITE CRYSTALLINE)	1 Kg.	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	1.375 kg.
		2	ACETONE	1.971 kg.
		4	METHYLENE CHLORIDE MC	3.29 kg.
		5	2 MERCAPTO BENZO THIAZOLE MBT	0.511 kg.
		6	METHANOL	1.971 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	117 / NC/3/MEET/Mar/202223/22				
Case Status	Case Approved				
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023				
HQ File Number	HQRNORM APPLY 00003797AM23				
RA File Number	31AX04000194 AM23				
Licence No and Date	3111001751/18/10/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.

1	ETHYLENEDIAMINE (ORGANIC CHEMICAL)	1 kg	1	MONO ETHANOL AMINE	1.03 kg
			2	AMMONIA ANHYDROUS	Not allowed
2	DI ETHYLENE TRIAMINE(ORGANIC CHEMICAL)	1 kg	1	MONO ETHANOL AMINE	1.184 kg
			2	AMMONIA ANHYDROUS	Not allowed
3	AMINO ETHYL ETHANOL AMINE(ORGANIC CHEMICAL)	1 kg	1	MONO ETHANOL AMINE	1.1731 kg

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

Case No.	118 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003801AM23
RA File Number	09AX04000575 AM23
Licence No and Date	0911003827/18/10/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: i. Percentage composition of Export Product. ii. Step wise manufacturing process. iii. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. iv. Complete technical details as per Annexure to Appendix 4E for chemical products. v. Stoichiometric balance between import and export on molar basis. vi. Details of indigenous input with quantity.	

Case No.	119 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003805AM23

RA File Number	09AX04000612 AM23			
Licence No and Date	0911003830/18/10/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and 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. (in Kg.)
L-MENTHYL GLYOXYLATE HYDRATE (L-MGH)(L-MENTHYL GLYOXYLATE HYDRATE (L-MGH))	1 kg.	1	GLYOXALIC ACID 50PCT	0.752
		2	CYCLOHEXANE	1.41
		3	L MENTHOL FRESH RECOVERY	0.45

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

Case No.	120 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003808AM23
RA File Number	09AX04000551 AM23
Licence No and Date	0911003834/18/10/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and 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:	

Clavulanate Potassium equivalent to Clavulanic acid 125 mg))		3	Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)	2.25 mg
		4	Potassium Clavulanate Diluted with Microcrystalline Cellulose (1:1)	302.03 mg

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

Case No.	121 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003824AM23
RA File Number	07AX04001015 AM23
Licence No and Date	0711005482/19/10/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm	
(i) Copy of Master-Batch Formula showing net contents of inputs in Tablets.	

Case No.	122 / NC/3/MEET/Mar/202223/22				
Case Status	Case Approved				
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023				
HQ File Number	HQRNORM APPLY 00003829AM23				
RA File Number	03AX04003555 AM23				
Licence No and Date	0311018709/19/10/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.

1	CLINDAMYCIN HYDRCHLORIDE 150MG CAPSULES	1 Number	1	Clindamycin Hydrochloride	171.05 mg / 150 mg capsule
2	CLINDAMYCIN HYDRCHLORIDE 300MG CAPSULES	1 Number	1	Clindamycin Hydrochloride	341.20 mg / 300 mg capsule

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

Case No.	123 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003858AM23
RA File Number	52AX04001677 AM23
Licence No and Date	5211003490/20/10/2022
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. 10/82-ALC4/2019 dated 29.11.2019 against advance authorization No. 5210043165 dated 30.08.2019 , 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:	

Case No.	124 / NC/3/MEET/Mar/202223/22			
Case Status	Case Approved			
Party Name	TITAN LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023			
HQ File Number	HQRNORM APPLY 00003861AM23			

RA File Number	03AX04003762 AM23			
Licence No and Date	0311018753/20/10/2022			
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/Nov/202223/12 dated 18/11/2022 against advance authorization No. 0311011408 dated 15/02/2022, 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.
ORLISTAT PELLETS 50 %	1 kg	1	ORLISTAT	0.505 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	125 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	HAFFKINE BIO PHARMACEUTICAL CORPORATION LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003863AM23
RA File Number	03AX04003507 AM23
Licence No and Date	0311018754/20/10/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and on the basis of written comments furnished by Department of Biotechnology for similar case of the firm, it was decided to call for following information / documents from the firm: i. Technical process flow diagram of manufacturing of Bivalent (Type I & Type III) Oral Poliomyelitis Vaccine and wastage involved at each step. ii. DML (Drug Manufacturing License).	

Case No.	126 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003865AM23
RA File Number	08AX04001228 AM23

Licence No and Date	0811006315/20/10/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to ratify adhoc norms as per SION A-412. RA concerned may take further necessary action as per above decision of NC.	

Case No.	127 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	MISTAIR HEALTH AND HYGIENE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003866AM23
RA File Number	03AX04003730 AM23
Licence No and Date	0311018761/21/10/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:- 1. Copy of DML for the composition shown in export item. 2. Master-Batch Formula for above export.	

Case No.	128 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003867AM23
RA File Number	07AX04001068 AM23
Licence No and Date	0711005519/21/10/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	129 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003884AM23

RA File Number	05AX04001931 AM23
Licence No and Date	0511015457/21/10/2022

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/Feb/202223/21 dated 22/02/2023** against advance authorization No. **0511004616 dated 08/09/2021**, 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.
CEFTIBUTEN USP/BP/EP/JP (POWDER)	1 kg	1	PENICILLIN G POTASSIUM FIRST CRYSTAL	8.515 kg
		2	METHYLENE CHLORIDE /Dichloromethane	76.165 kg
		3	Triethylamine	3.214 kg
		4	Methanol	41.137 kg
		5	Ethyl 4 Chloroacetoacetate	1.82 kg
		6	Methyl 3 Methoxy Acrylate	1.62 kg
		7	Prenol	3.114 kg
		8	N N Dimethyl Formamide	12.16 kg
		9	Acetonitile	7.50 kg
		10	Activated Carbon	0.200 kg
		11	Acetone	1.20 kg
		12	Toluene	23.00 kg
		13	Acetic Acid	5.50 kg

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

Case No.	130 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003896AM23
RA File Number	07AX04001078 AM23
Licence No and Date	0711005538/21/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	131 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003897AM23
RA File Number	07AX04001077 AM23
Licence No and Date	0711005539/21/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	132 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003898AM23
RA File Number	07AX04001085 AM23
Licence No and Date	0711005540/21/10/2022
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/Jan/202223/18 dated 23/01/2023 against advance authorization No. 0711000991 dated 27/04/2021, 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.
MAGNESIUM BISGLYCINATE / MAGNESIUM GLYCINE COMPLEX	1 kg	1	GLYCINE	0.97 kg
		2	MAGNESIUM OXIDE	0.26 kg

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

Case No.	133 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003899AM23
RA File Number	07AX04001086 AM23
Licence No and Date	0711005541/21/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	134 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003901AM23
RA File Number	03AX04003806 AM23
Licence No and Date	0311018798/22/10/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:	
i. Step wise manufacturing process. ii. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. iii. Complete technical details as per Annexure to Appendix 4E for chemical products.	

- iv. **Stoichiometric balance between import and export on molar basis**
v. **Details of indigenous input with quantity.**

Case No.	135 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003910AM23
RA File Number	30AX04000299 AM23
Licence No and Date	3011002731/25/10/2022
Norms Committee Decision: The Committee considered the case as per agenda and on the basis of written comments furnished by Department of Biotechnology for similar case of the firm, it was decided to call for following information / documents from the firm: i. Justification for claiming 20% wastage. ii. Import input, that is, Urokinase in terms of IU/mg. iii. DML (Drug Manufacturing License).	

Case No.	136 / NC/3/MEET/Mar/202223/22			
Case Status	Case Approved			
Party Name	AUROBINDO PHARMA LTD			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023			
HQ File Number	HQRNORM APPLY 00003913AM23			
RA File Number	09AX04000522 AM23			
Licence No and Date	0911003867/25/10/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and 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.
Amoxicillin Tablets 875 mg((Each Tablet contains Amoxicillin Trihydrate equivalent to Amoxicillin 875mg))	1 Number	1	6-Amino Penicillanic Acid	576.40 mg.
		2	D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]	496.38 mg.
		3	Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped	2.25 mg.

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

Case No.	137 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003914AM23
RA File Number	08AX04001242 AM23
Licence No and Date	0811006339/25/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	138 / NC/3/MEET/Mar/202223/22																		
Case Status	Case Approved																		
Party Name	GLAND PHARMA LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023																		
HQ File Number	HQRNORM APPLY 00003917AM23																		
RA File Number	09AX04000410 AM22																		
Licence No and Date	0911002854/26/10/2022																		
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. 0911003095 dated 02/06/2022 , 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:																			
<table><tr><th>Sl. No.</th><th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr><tr><td rowspan="3">1</td><td rowspan="3">Nadroparin Calcium Injection (Low Molecular Weight Heparin) 2850 IU/0.3ml PFS(IU)</td><td rowspan="3">1 Number</td><td>1</td><td>Nadroparin Calcium</td><td>26.125 mg</td></tr><tr><td>2</td><td>Barrel Syringes</td><td>1.05 Numbers</td></tr><tr><td>3</td><td>Plunger Stoppers</td><td>1.1085 Numbers</td></tr></table>		Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.	1	Nadroparin Calcium Injection (Low Molecular Weight Heparin) 2850 IU/0.3ml PFS(IU)	1 Number	1	Nadroparin Calcium	26.125 mg	2	Barrel Syringes	1.05 Numbers	3	Plunger Stoppers	1.1085 Numbers
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.														
1	Nadroparin Calcium Injection (Low Molecular Weight Heparin) 2850 IU/0.3ml PFS(IU)	1 Number	1	Nadroparin Calcium	26.125 mg														
			2	Barrel Syringes	1.05 Numbers														
			3	Plunger Stoppers	1.1085 Numbers														

			4	Plunger Rods	1.0165 Numbers
			5	Preventis	1.05 Numbers
2	Nadroparin Calcium Injection (Low Molecular Weight Heparin) 5700 IU/0.6ml PFS(IU)	1 Number	1	Nadroparin Calcium	52.25 mg
			2	Barrel Syringes	1.05 Numbers
			3	Plunger Stoppers	1.1085 Numbers
			4	Plunger Rods	1.0165 Numbers
			5	Preventis	1.05 Numbers

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

Case No.	139 / NC/3/MEET/Mar/202223/22			
Case Status	Case Approved			
Party Name	LYRUS LIFE SCIENCES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023			
HQ File Number	HQRNORM APPLY 00003921AM23			
RA File Number	07AX04001039 AM23			
Licence No and Date	0711005556/27/10/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and 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.
BEZAFIBRATE Tablet 400 mg	1 Number	1	BEZAFIBRATE	400.00 mg / Tablet

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

Case No.	140 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003925AM23
RA File Number	09AX04000647 AM23
Licence No and Date	0911003881/27/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	141 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003935AM23
RA File Number	03AX04003741 AM23
Licence No and Date	0311018893/27/10/2022

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/Jan/202223/18 dated 23/01/2023** against advance authorization No. **0311017259 dated 16/08/2022**, 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:

(A)

Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	ALLOPURINOL TABLETS 100MG (Each Allopurinol Tablet of 100mg contains Allopurinol 100mg)(Equivalent to:-Cyano Acetamide 0.0001mg,Triethyl Ortho formate 0.00021mg, Formamide 0.00015 mg, Morpholine 0.00013mg, Hydrazine Hydrate 0.00006 mg) Net wt of Allopurinol 15000 kgs (Cross Norms of Allopurinol SION No.A2321 & Tablets/Capsules A412))	1 Number	1	Allopurinol	102.00 mg / 100 mg Tablet
2	ALLOPURINOL TABLETS 300MG (Each	1 Number	2	Allopurinol	306.00 mg / 300

	Allopurinol Tablet of 300mg contains Allopurinol 300 mg)(Equivalent to:-Cyano Acetamide 0.0003mg ,Triethyl Ortho-formate 0.00063mg, Formamide 0.00045 mg, Morpholine 0.00039mg , Hydrazine Hydrate 0.00018 mg) Net wt of Allopurinol 15000 kgs. (Cross Norms of Allopurinol SION No.A2321 & Tablets/Capsules A412))				mg Tablet
--	---	--	--	--	-----------

(B)

Export product	Qty.	Sl. No.	Import items	Qty.
ALLOPURINOL	1 kg	1	Cyano Acetamide	1.00 kg
		2	Triethyl Ortho formate	2.10 kg
		3	Formamide	1.50 kg
		4	Morpholine	1.30 kg
		5	Hydrazine Hydrate	0.60 kg

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

Case No.	142 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003936AM23
RA File Number	03AX04003679 AM23
Licence No and Date	0311018894/27/10/2022

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/Jan/202223/18 dated 23/01/2023** against advance authorization No. **0311018302 dated 30/09/2022**, 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Benzydamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and (other flavours. Each lozenge contains (i) Benzydamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride- 1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 31.034 Kgs (ii) 13.759 Kgs (iii) 26751.736 Kgs.)	1000 Number	1	Benzydamine Hydrochloride	3.06 gram
			2	Cetylpyridinium Chloride	1.356 gram
			3	Isomalt ST-M	2586.00 gram
2	Benzydamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory, (Anti-Inflammatory, Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg. Net content (i) 25.926 Kgs. (ii) 22348.129 Kgs.)	1000 Number	4	Benzydamine Hydrochloride	3.06 gram
			5	Isomalt ST-M	2586.00 gram
3	Benzydamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free. (Each lozenge contains (i) Benzydamine Hydrochloride- 3mg (ii) Isomalt ST-M - 2586mg. Net content (i) 13.333 Kgs. (ii) 11493.343 Kgs.)	1000 Number	6	Benzydamine Hydrochloride	3.06 gram
			7	Isomalt ST-M	2586.00 gram
4	Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours. (Each (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 1.968 Kg (ii) 3825.997 Kg.)	1000 Number	8	Cetylpyridinium Chloride	1.356 gram
			9	Isomalt ST-M	2586.00 gram

5	Cetylpyridinium Chloride And Benzylamine Hydrochloride Antiseptic Lozenges Sugar Free.(Each lozenge contains (i) Cetylpyridinium Chloride- 1 mg (ii) Isomalt ST-M - 2586mg. Net content (i) 1.333 Kg (ii) 3448.028 Kg)	1000 Number	10	Cetylpyridinium Chloride	1.02 gram
			11	Isomalt ST-M	2586.00 gram

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

Case No.	143 / NC/3/MEET/Mar/202223/22				
Case Status	Case Approved				
Party Name	AARTI DRUGS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023				
HQ File Number	HQRNORM APPLY 00003937AM23				
RA File Number	03AX04002927 AM23				
Licence No and Date	0311018896/27/10/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and 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.	
Ciprofloxacin Hydrochloride USP	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg	
		2	Piperazine Anhydrous	0.390 kg.	
RA concerned may take further necessary action as per above decision of NC.					

Case No.	144 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003938AM23
RA File Number	03AX04002933 AM23
Licence No and Date	0311018897/27/10/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and 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.
Ciprofloxacin Hydrochloride USP	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg

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

Case No.	145 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003939AM23
RA File Number	03AX04003168 AM23
Licence No and Date	0311018898/27/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Ciprofloxacin Hydrochloride USP	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg

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

Case No.	146 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003940AM23
RA File Number	03AX04002984 AM23

Licence No and Date	0311018899/27/10/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and 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.
Ciprofloxacin Hydrochloride USP	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	147 / NC/3/MEET/Mar/202223/22			
Case Status	Case Approved			
Party Name	RUMIT LIFE CARE			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023			
HQ File Number	HQRNORM APPLY 00003941AM23			
RA File Number	03AX04003823 AM23			
Licence No and Date	0311018900/28/10/2022			
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/Nov/202223/12 dated 18/11/2022 against advance authorization No. 0311013605 dated 04/04/2022 , 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.
Betamethasone Dipropionate IP/BP/EP/USP	1 kg	1	Betamethasone IP/BP/EP/USP	0.868 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	148 / NC/3/MEET/Mar/202223/22			
Case Status	Case Approved			

Party Name	AUROBINDO PHARMA LTD																			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023																			
HQ File Number	HQRNORM APPLY 00003943AM23																			
RA File Number	09AX04000083 AM23																			
Licence No and Date	0911003884/28/10/2022																			
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/202223/17 dated 13/01/2023 against advance authorization No. 0911002574 dated 01/03/2022, 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: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Amoxicillin Tablets 875 mg((Each tablet contains Amoxicillin Trihydrate equivalent to Amoxicillin 875mg & the relevant bulk drug content in the export product 87,500 kg))</td> <td rowspan="3">1 Number</td> <td>1</td> <td>6-APA</td> <td>576.40 mg</td> </tr> <tr> <td>2</td> <td>Methyl d-(-)-4-hydroxy-phenylglycinate OR D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]</td> <td>496.39 mg</td> </tr> <tr> <td>3</td> <td>Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)</td> <td>2.25 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.	Amoxicillin Tablets 875 mg((Each tablet contains Amoxicillin Trihydrate equivalent to Amoxicillin 875mg & the relevant bulk drug content in the export product 87,500 kg))	1 Number	1	6-APA	576.40 mg	2	Methyl d-(-)-4-hydroxy-phenylglycinate OR D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]	496.39 mg	3	Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)	2.25 mg
Export product	Qty.	Sl. No.	Import items	Qty.																
Amoxicillin Tablets 875 mg((Each tablet contains Amoxicillin Trihydrate equivalent to Amoxicillin 875mg & the relevant bulk drug content in the export product 87,500 kg))	1 Number	1	6-APA	576.40 mg																
		2	Methyl d-(-)-4-hydroxy-phenylglycinate OR D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]	496.39 mg																
		3	Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)	2.25 mg																

Case No.	149 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003945AM23
RA File Number	34AX04000703 AM23
Licence No and Date	3411002947/28/10/2022
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/Jan/202223/18 dated 23/01/2023 against advance authorization No. 3411002686 dated 26/08/2022, 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.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	150 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003946AM23
RA File Number	34AX04000702 AM23
Licence No and Date	3411002948/28/10/2022

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/Jan/202223/18 dated 23/01/2023** against advance authorization No. **3411002686 dated 26/08/2022**, 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.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	151 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003948AM23

RA File Number	07AX04001102 AM23
Licence No and Date	0711005565/28/10/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	152 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003952AM23
RA File Number	09AX04000552 AM23
Licence No and Date	0911003887/28/10/2022

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. **0911003357 dated 15/07/2022**, 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Cefalexin Tablets 250mg(Cephalexin Tablets 250mg (Each film coated tablet contains Cefalexin Monohydrate Ph.Eur equivalent to anhydrous Cefalexin 250mg))	1 Number	1	Cefalexin Monohydrate Ph Eur (Powder)	268.2 mg / 250 mg Tablet
2	Cefalexin Tablets 500mg(Cephalexin Tablets 500mg (Each film coated tablet contains Cefalexin Monhydrate Ph.Eur equivalent to anhydrous Cefalexin 500mg))	1 Number	2	Cefalexin Monohydrate Ph Eur (Powder)	536.4 mg / 500 mg Tablet

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

Case No.	153 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003964AM23
RA File Number	03AX04003413 AM23
Licence No and Date	0311018931/31/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Ciprofloxacin Hydrochloride USP	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg

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

Case No.	154 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003965AM23
RA File Number	03AX04003608 AM23
Licence No and Date	0311018932/31/10/2022

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/Jan/202223/18 dated 23/01/2023** against advance authorization No. **0311018302 dated 30/09/2022**, 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:

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

1	Benzydamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and (other flavours. Each lozenge contains (i) Benzydamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride- 1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 31.034 Kgs (ii) 13.759 Kgs (iii) 26751.736 Kgs.)	1000 Number	1	Benzydamine Hydrochloride	3.06 gram
			2	Cetylpyridinium Chloride	1.356 gram
			3	Isomalt ST-M	2586.00 gram
2	Benzydamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory, (Anti-Inflammatory, Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg. Net content (i) 25.926 Kgs. (ii) 22348.129 Kgs.)	1000 Number	4	Benzydamine Hydrochloride	3.06 gram
			5	Isomalt ST-M	2586.00 gram
3	Benzydamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free. (Each lozenge contains (i) Benzydamine Hydrochloride- 3mg (ii) Isomalt ST-M - 2586mg. Net content (i) 13.333 Kgs. (ii) 11493.343 Kgs.)	1000 Number	6	Benzydamine Hydrochloride	3.06 gram
			7	Isomalt ST-M	2586.00 gram
4	Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours. (Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 1.968 Kg (ii) 3825.997 Kg.) lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 1.968 Kg (ii) 3825.997 Kg.)	1000 Number	8	Cetylpyridinium Chloride	1.356 gram
			9	Isomalt ST-M	2586.00 gram
5	Cetylpyridinium Chloride And Benzydamine Hydrochloride Antiseptic Lozenges Sugar Free. (Each lozenge contains (i) Cetylpyridinium Chloride- 1 mg (ii) Isomalt ST-M - 2586mg. Net content (i) 1.333 Kg (ii) 3448.028 Kg)	1000 Number	10	Cetylpyridinium Chloride	1.02 gram
			11	Isomalt ST-M	2586.00 gram

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

Case No.	155 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003979AM23
RA File Number	03AX04002468 AM23
Licence No and Date	0311018957/31/10/2022

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/Aug/202223/6 dated 09/09/2022** against advance authorization No. **0311010807 dated 24/01/2022**, 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:

Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	GLIPIZIDE EXTENDED RELEASE TABLETS 10 MG. Each tablet contains (i) Glipizide USP- 10 mg(ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 29.70 mg (iii) Sentry Polyox WSR N80 FP NF- 178.10 mg (iv) Sentry Polyox WSR 303 NF- 100 mg. Net content (i) 317.12 Kgs (ii) 941.84 Kgs (iii) 5647.85 Kgs (iv) 3171.17 Kgs.)	1 Number	1	GLIPIZIDE USP	10.20 mg
			2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	29.70 mg
			3	SENTRY POLYOX WSR N80 FP NF	178.10 mg
			4	SENTRY POLYOX WSR 303 NF	100.00 mg
2	GLIPIZIDE EXTENDED RELEASE TABLETS 5 MG. Each tablet contains (i) Glipizide USP- 5 mg(ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 20.40 mg (iii) Sentry Polyox WSR N80 FP NF- 89.05 mg (iv) Sentry Polyox WSR 303 NF- 50 mg. Net content (i) 256.76 Kgs (ii) 1047.57 Kgs (iii) 4572.84 Kgs (iv)	1 Number	5	GLIPIZIDE USP	5.10 mg
			6	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	20.40 mg
			7	SENTRY POLYOX WSR N80 FP NF	89.05 mg

	2567.57 Kgs.)		8	SENTRY POLYOX WSR 303 NF	50.00 mg
3	GLIPIZIDE EXTENDED RELEASE TABLETS 2.5 MG. Each tablet contains (i) Glipizide USP- 2.5 mg(ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 20.40 mg (iii) Sentry Polyox WSR N80 FP NF- 89.05 mg (iv) Sentry Polyox WSR 303 NF- 50 mg. Net content (i) 101.80 Kgs (ii) 830.70 Kgs (iii) 3626.18 Kgs (iv) 2036.04 Kgs.)	1 Number	9	GLIPIZIDE USP	2.55 mg
			10	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	20.40 mg
			11	SENTRY POLYOX WSR N80 FP NF	89.05 mg
			12	SENTRY POLYOX WSR 303 NF	50.00 mg

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

Case No.	156 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003982AM23
RA File Number	05AX04002096 AM23
Licence No and Date	0511015534/31/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:

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

Case No.	157 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AROHEMA INGREDIENTS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023													
HQ File Number	HQRNORM APPLY 00003984AM23													
RA File Number	26AX04000062 AM23													
Licence No and Date	2611000750/31/10/2022													
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/Feb/202223/21 dated 22/02/2023 against advance authorization No. 2611000488 dated 03/03/2022, 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: <table border="1" data-bbox="197 750 1430 1031"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">ORCANOX</td> <td rowspan="2">1 kg</td> <td>1</td> <td>SCLAREOLIDE (90% purity)</td> <td>1.4987 kg</td> </tr> <tr> <td>2</td> <td>TERT - AMYL ALCOHOL</td> <td>2.64 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.	ORCANOX	1 kg	1	SCLAREOLIDE (90% purity)	1.4987 kg	2	TERT - AMYL ALCOHOL	2.64 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
ORCANOX	1 kg	1	SCLAREOLIDE (90% purity)	1.4987 kg										
		2	TERT - AMYL ALCOHOL	2.64 kg										

Case No.	158 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	NECTAR LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003987AM23
RA File Number	302404000100 AM20
Licence No and Date	3011002766/01/11/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	159 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	BRAWN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003991AM23
RA File Number	05AX04001882 AM23
Licence No and	0511015547/01/11/2022

Date	
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	160 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SUNSHIELD CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003993AM23
RA File Number	03AX04003805 AM23
Licence No and Date	0311018972/01/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:-	
i. Molecular weight of reactant & finished product ii. Balance Chemical Reaction iii. Percentage yields at every stage of reaction.	

Case No.	161 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003994AM23
RA File Number	31AX04000219 AM23
Licence No and Date	3111001777/01/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and 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:	

2	DI ETHYLENE TRIAMINE(ORGANIC CHEMICAL)	1 kg	3	MONO ETHANOL AMINE	1.184 kg
			4	AMMONIA ANHYDROUS	Not allowed, as it is shown indigenous
3	AMINO ETHYL ETHANOL AMINE(ORGANIC CHEMICAL)	1 kg	5	MONO ETHANOL AMINE	1.1731 kg
4	AMINO ETHYL PIPERAZINE(ORGANIC CHEMICAL)	1 kg	6	MONO ETHANOL AMINE	1.07 kg

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

Case No.	162 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00003997AM23
RA File Number	31AX04000213 AM23
Licence No and Date	3111001781/01/11/2022

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/Jan/202223/18 dated 23/01/2023** against advance authorization No. **3111001669 dated 02/09/2022**, 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.
MORPHOLINE (ORGANIC CHEMICAL)	1 kg	1	DIETHYLENE GLYCOL	1.279 kg
		2	AMMONIA ANHYDROUS	0.217 kg
		3	HYDROGEN	Not allowed, as it is procured indigenously.

		4	MORPHOLINE CATALYST	Not allowed as no catalogue is available.
--	--	---	---------------------	---

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

Case No.	163 / NC/3/MEET/Mar/202223/22			
Case Status	Case Approved			
Party Name	SENTISS PHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023			
HQ File Number	HQRNORM APPLY 00004011AM23			
RA File Number	05AX04002187 AM23			
Licence No and Date	0511015561/01/11/2022			
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/May/202223/4 dated 17/06/2022 against advance authorization No. 0511002009 dated 31/03/2021 , 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:				

Case No.	164 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004012AM23
RA File Number	05AX04002188 AM23
Licence No and Date	0511015564/01/11/2022
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. **0511012971 dated 02/06/2022**, 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
Kombinil-DUO Eye/Ear Drops 5ml Vial (5 mg per vial)	1 Pack	1	Dexamethasone Micronised PH EUR USP JP	5.10 mg

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

Case No.	165 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004013AM23
RA File Number	05AX04002178 AM23
Licence No and Date	0511015565/01/11/2022

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/202223/18 dated 23/01/2023** against advance authorization No. **0511014295 dated 16/08/2022**, 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.
Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml	1 Vial	1	Brinzolamide	51.00 mg / Vial

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

Case No.	166 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004014AM23
RA File Number	05AX04002182 AM23
Licence No and Date	0511015566/01/11/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: Get the Advance Authorization amended from concerned RA indicating content of API in 5ml pack	

Case No.	167 / NC/3/MEET/Mar/202223/22										
Case Status	Case Approved										
Party Name	SENTISS PHARMA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023										
HQ File Number	HQRNORM APPLY 00004015AM23										
RA File Number	05AX04002181 AM23										
Licence No and Date	0511015567/01/11/2022										
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/202223/18 dated 23/01/2023 against advance authorization No. 0511014295 dated 16/08/2022 , 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:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml</td><td>1 Vial</td><td>1</td><td>Brinzolamide</td><td>51.00 mg / Vial</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml	1 Vial	1	Brinzolamide	51.00 mg / Vial
Export product	Qty.	Sl. No.	Import items	Qty.							
Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml	1 Vial	1	Brinzolamide	51.00 mg / Vial							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	168 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved

Party Name	RECKITT BENCKISER (INDIA) PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023				
HQ File Number	HQRNORM APPLY 00004017AM23				
RA File Number	05AX04002179 AM23				
Licence No and Date	0511015570/01/11/2022				
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/202223/8 dated 23/09/2022 against advance authorization No. 0511005203 dated 05/10/2021, 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	DISPRIN REGULAR (ASPIRIN PH.EUR 300MG)(ACETYL SALICYLIC ACID 300 mg Tablet (ASPIRIN))	1 Number Tablet	1	CITIRIC ACID ANHYDROUS F4020	30.00 mg
			2	SACCHARIN BASE 550x	4.50 mg
			3	CALCIUM CARBONATE EP	90.00 mg
2	DISPRIN,ZA,EXTRA (ASPIRIN PH.EUR 500MG)(ACETYL SALICYLIC ACID 500 mg Tablet (ASPIRIN))	1 Number Tablet	4	CITIRIC ACID ANHYDROUS F4020	50.00 mg
			5	SACCHARIN BASE 550x	7.50 mg
			6	CALCIUM CARBONATE EP	150.00 mg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	169 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	REYAANSH HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004021AM23
RA File Number	03AX04003763 AM23
Licence No and	0311018994/02/11/2022

Date	
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	170 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004025AM23
RA File Number	04AX04000654 AM23
Licence No and Date	0411004350/02/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	171 / NC/3/MEET/Mar/202223/22										
Case Status	Case Approved										
Party Name	PARUL CHEMICALS										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023										
HQ File Number	HQRNORM APPLY 00004027AM23										
RA File Number	34AX04000699 AM23										
Licence No and Date	3411002956/02/11/2022										
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/202223/11 dated 31/10/2022 against advance authorization No. 0311009858 dated 28/12/2021 , 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:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Triethyl citrate</td><td>1 kg</td><td>1</td><td>Citric Acid Anhydrous</td><td>0.7322 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Triethyl citrate	1 kg	1	Citric Acid Anhydrous	0.7322 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
Triethyl citrate	1 kg	1	Citric Acid Anhydrous	0.7322 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	172 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred

Party Name	SHIVA BIO CHEM INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004047AM23
RA File Number	50AX04000064 AM23
Licence No and Date	5011000667/03/11/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: i. Complete COA of Export Product indicating percentage content of each item in it. ii. Complete COA of import item from foreign supplier indicating percentage content of each item in it. iii. Wastage at each stage of manufacturing.	

Case No.	173 / NC/3/MEET/Mar/202223/22				
Case Status	Case Approved				
Party Name	VEKO CARE PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023				
HQ File Number	HQRNORM APPLY 00004048AM23				
RA File Number	31AX04000216 AM23				
Licence No and Date	3111001792/03/11/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. (in KG)
(i)	Assurity Plus SPOT ON (For Small Cat) (Pack size 0.4ml x 6 pipettes)(Each ml contains Imidacloprid 100mg, Net Weight = 0.240 Kgs)	1000 number	1	Imidacloprid	0.245
(ii)	Assurity Plus SPOT ON (For Large Cat) (Pack size 0.8ml x 6 pipettes)(Each ml contains: Imidacloprid 100mg, Net Weight = 0.480 Kgs)	1000 number	2	Imidacloprid	0.49

(ii)	Assurity Plus SPOT ON (For Small Dog) (Pack size 0.4ml x 6 Pipettes), (Each ml contains: Imidacloprid 10%, Net Weight = 0.240 Kgs)	1000 number	3	Imidacloprid	0.245
(iv)	Assurity Plus SPOT ON (For Medium Dog) (Pack size 1ml x 6 Pipettes)(Each ml contains: Imidacloprid 10% , Net Weight = 0.600 Kgs)	1000 number	4	Imidacloprid	0.612
(v)	Assurity Plus SPOT ON (For Large Dog) (Pack size 2.5ml x 6 Pipettes) (Each ml contains: Imidacloprid 10% , Net Weight = 1.500 Kgs)	1000 number	5	Imidacloprid	1.53
(vi)	Assurity Plus SPOT ON (For Extra Large Dog) (Pack size 4ml x 6 Pipettes) (Each ml contains: Imidacloprid 10% , Net Weight = 2.400 Kgs)	1000 number	6	Imidacloprid	2.448
(vii)	Banfle II Plus SPOT ON (For Extra Large Dog) (Pack size 4ml x 6 Pipettes) (Each ml contains: Imidacloprid 88mg, Net Weight = 1.056 Kgs)	500 number	7	Imidacloprid	1.077
(viii)	Banfle II Plus Spot on for Dog (For Large Dog) (Pack size 2.5ml x 6 Pipettes) (Each ml contains: Imidacloprid 88mg, Net Weight = 0.660 Kgs)	500 number	8	Imidacloprid	0.673
(ix)	Banfle II Plus Spot on for Dog (For Medium Dog) (Pack size 1ml x 6 Pipettes) (Each ml contains: Imidacloprid 88mg, Net Weight = 0.317 Kgs)	600 number	9	Imidacloprid	0.323
(x)	Banfle II Plus Spot on for Dog (For Small Dog) (Pack size 0.4ml x 6 Pipettes), (Each ml contains: Imidacloprid 88mg, Net Weight = 0.127 Kgs)	600 number	10	Imidacloprid	0.129
(xi)	Banfle Plus for Dog (For Small Dog) (Pack size 0.4ml x 6 Pipettes),(Each ml contains: Imidacloprid 91mg, Net Weight = 0.131 Kgs)	600 number	11	Imidacloprid	0.134
(xii)	Banfle Plus for Dog (For Medium Dog) (Pack size 1ml x 6 Pipettes), (Each ml contains: Imidacloprid 91mg, Net Weight = 0.273 Kgs)	500 number	12	Imidacloprid	0.278
(xiii)	Banfle Plus for Dog (For Large Dog) (Pack size 2.5ml x 6 Pipettes), (Each ml contains: Imidacloprid 91mg, Net Weight = 0.683 Kgs)	500 number	13	Imidacloprid	0.696

(xiv)	Banflea Plus for Dog (For Extra Large Dog) (Pack size 4ml x 6 Pipettes), (Each ml contains: Imidacloprid 91mg, Net Weight = 1.092 Kgs)	500 number	14	Imidacloprid	1.114
-------	--	------------	----	--------------	-------

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

Case No.	174 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	VASISTA LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004049AM23
RA File Number	09AX04000675 AM23
Licence No and Date	0911003903/03/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	175 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004053AM23
RA File Number	31AX04000225 AM23
Licence No and Date	3111001793/03/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. (in Kg.)
(i)	Radicat Spot on 6% for Cats (Pack size 0.75ml x 6 pipettes),(Each ml contains: Selamectin BP 60mg, Net Weight = 1.215 Kgs)	4500 Number	1	Selamectin BP / EP / USP	1.239
(ii)	Radicat Spot on 6% for Cats (Pack size 0.75ml x 1 pipettes),(Each ml contains: Selamectin BP 60mg, Net Weight = 0.086	1900 Number	2	Selamectin BP / EP / USP	0.088

	Kgs)				
(iii)	Radicat Spot on 12% for Dog (Small Dog) (Pack size 0.5ml x 1 pipettes),(Each ml contains: Selamectin BP 12%, Net Weight = 0.060 Kgs)	1000 Number	3	Selamectin BP / EP / USP	0.0612
(iv)	Radicat Spot on 12% for Dog (Medium Dog) (Pack size 1 ml x 1 pipettes),(Each ml contains: Selamectin BP 12%, Net Weight = 0.120 Kgs)	1000 Number	4	Selamectin BP / EP / USP	0.1224
(v)	Radicat Spot on 12% for Dog (Large Dog) (Pack size 2 ml x 1 pipettes)(Each ml contains: Selamectin BP 12%, Net Weight = 0.240 Kgs)	1000 Number	5	Selamectin BP / EP / USP	0.245
(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 = 0.180 Kgs)	500 Number	6	Selamectin BP / EP / USP	0.184
RA concerned may take further necessary action as per above decision of NC.					

Case No.	176 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004054AM23
RA File Number	31AX04000221 AM23
Licence No and Date	3111001794/03/11/2022

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/Nov/202223/14 dated 07/12/2022** against advance authorization No. **0311010772 dated 21/01/2022**, 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:

Sl. No.	Export Product	Qty	Sl. No.	Import Items	Qty
1	Sodium Chloride 0.9% 100ml	1 Number	1	Sodium Chloride (SANAL)(EP)	0.945 gram

2	Sodium Chloride 0.9% 500ml	1 Number	2	Sodium Chloride (SANAL)(EP)	4.725 gram
3	Sodium Chloride 0.9% 1000ml	1 Number	3	Sodium Chloride (SANAL)(EP)	9.450 gram

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

Case No.	177 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004067AM23
RA File Number	09AX04000690 AM23
Licence No and Date	0911003904/04/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Escitalopram Tablets 10mg([Each film coated tablet contains Escitalopram Oxalate equivalent to 10mg Escitalopram])	1 number	1	Escitalopram Oxalate	13.03 mg.
Escitalopram Tablets 20mg([Each film coated tablet contains Escitalopram Oxalate equivalent to 20mg Escitalopram])	1 number	2	Escitalopram Oxalate	26.06 mg.

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

Case No.	178 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	LASENOR INDIA PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004068AM23
RA File Number	50AX04000062 AM23
Licence No and Date	5011000669/04/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	179 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004071AM23
RA File Number	09AX04000645 AM23
Licence No and Date	0911003906/04/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	180 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	AMARA LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004072AM23
RA File Number	09AX04000646 AM23
Licence No and Date	0911003907/04/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	181 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004119AM23
RA File Number	07AX04001127 AM23
Licence No and Date	0711005625/07/11/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and 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.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 4mcg/mL, 100ml Vial	1 Number	1	WPS S10-F451 4432/50G B240 WESTARRS/SP16 (20mm Serum Stopper - WPS-S10-F451 4432/50 GREY FLU)	Relevant as per packing policy

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

Case No.	182 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	S.V.CHEM INTERMEDIATES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004122AM23
RA File Number	04AX04000682 AM23
Licence No and Date	0411004409/07/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	CBZ-L-Valine(CBZ-L-Valine)	1 kg.	1	L - Valine	0.50 kg.

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

Case No.	183 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred

Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004123AM23
RA File Number	08AX04001251 AM23
Licence No and Date	0811006379/07/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	184 / NC/3/MEET/Mar/202223/22													
Case Status	Case Approved													
Party Name	TOPNOTCH CHEMICALS PVT LTD													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023													
HQ File Number	HQRNORM APPLY 00004164AM23													
RA File Number	03AX04003892 AM23													
Licence No and Date	0311019072/08/11/2022													
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/202223/17 dated 13/01/2023 against advance authorization No. 0310836133 dated 07/05/2020 , 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:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>ARTEMETHER</td><td>1 kg</td><td>1</td><td>ARTEMISININ</td><td>1.04 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	ARTEMETHER	1 kg	1	ARTEMISININ	1.04 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
ARTEMETHER	1 kg	1	ARTEMISININ	1.04 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	185 / NC/3/MEET/Mar/202223/22			
Case Status	Case Deferred			
Party Name	JUBILANT INGREVIA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023			
HQ File Number	HQRNORM APPLY 00004212AM23			
RA File Number	05AX04002149 AM23			
Licence No and Date	0511015679/09/11/2022			

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:

- i. Yield of reaction justifying the quantity of Propionic Acid asked for.
- ii. The details of recovery of Acetic Acid.

Case No.	186 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004214AM23
RA File Number	09AX04000708 AM23
Licence No and Date	0911003911/09/11/2022

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. **5/82-ALC4/2018 dated 25.07.2018** against advance authorization No. **0910063789 dated 10.06.2016**, 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.
METHYL HYDROXY BENZOATE BP	1 kg	1	PARA HYDROXY BENZOIC ACID	0.989 kg

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

Case No.	187 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004215AM23
RA File Number	09AX04000709 AM23
Licence No and Date	0911003912/09/11/2022

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/Jan/202122/13 dated 21/01/2022** against advance authorization No. **0910068574 dt. 13/03/2020**, 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.
PROPYL HYDROXY BENZOATE BP	1 kg	1	PARA HYDROXY BENZOIC ACID	0.80 kg

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

Case No.	188 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004216AM23
RA File Number	09AX04000689 AM23
Licence No and Date	0911003913/09/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm:

Percentage yield at every stage of reaction.

Case No.	189 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004217AM23
RA File Number	09AX04000688 AM23
Licence No and Date	0911003915/09/11/2022

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. **1/82-ALC4/2018 dated 01.05.2018** against advance authorization No. **0910064646 dated**

06.02.2017, 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.
BROSALIDOX-L (Containing minimum 10% of 5 Bromo-5 Nitro-1,3-Ploxane)	1 kg	1	PROPYLENE GLYCOL	0.90 kg

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

Case No.	190 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004218AM23
RA File Number	09AX04000687 AM23
Licence No and Date	0911003916/09/11/2022

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. **2/82-ALC4/2018 dated 16.05.2018** against advance authorization No. **0910062393 dated 28.07.2015**, 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.
OCTYL SALICYLATE	1 kg	1	METHYL SALICYLATE	0.58 kg

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

Case No.	191 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	VACHICHEM INTERNATIONAL PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023

and Date	
HQ File Number	HQRNORM APPLY 00004219AM23
RA File Number	07AX04001122 AM23
Licence No and Date	0711005637/09/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	192 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004220AM23
RA File Number	08AX04001249 AM23
Licence No and Date	0811006399/09/11/2022

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/Jan/202223/18 dated 23/01/2023** against advance authorization No. **0811002280 dated 09/08/2021**, 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.
NALTREXONE HYDROCHLORIDE TABLETS USP 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE USP 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 308.505 KGS.])	1 Number	1	NALTREXONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR (All Alcoholic Solvents and water content NLT 1.86% as per COA of import item)	51.93 mg / Tablet

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

Case No.	193 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	MAXTAR BIO GENICS

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004225AM23
RA File Number	05AX04002243 AM23
Licence No and Date	0511015686/09/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	194 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004249AM23
RA File Number	05AX04002217 AM23
Licence No and Date	0511015715/09/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. End use of export product. ii. Complete and balance chemistry, molecular weight and percentage yield on molar basis for each step of manufacturing process. iii. Past Production / Consumption of raw material certified by GST Authorities	

Case No.	195 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004250AM23
RA File Number	05AX04002186 AM23
Licence No and Date	0511015716/09/11/2022
Norms Committee Decision:	
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 following information / documents from the firm: i. Content of API is not given in export product. No norms can be fixed in its present form.	

Case No.	196 / NC/3/MEET/Mar/202223/22
----------	-------------------------------

Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
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 case as per agenda and decided to visit factory as there are large number of other similar cases of the company pending for ratification. Hence, the Committee decided to defer the case.	

Case No.	197 / NC/3/MEET/Mar/202223/22													
Case Status	Case Approved													
Party Name	GLENMARK PHARMACEUTICALS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023													
HQ File Number	HQRNORM APPLY 00004257AM23													
RA File Number	03AX04004010 AM23													
Licence No and Date	0311019118/10/11/2022													
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/Jan/202223/18 dated 23/01/2023 against advance authorization No. 0311017379 dated 22/08/2022 , 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:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Colesevelam HCL for oral suspension 3.75 GM (Per Pack 30 Pouches)((Net. Content of Colesevelam Hydrochloride is 472.50 kgs))</td><td>4200 Number Packs</td><td>1</td><td>Colesevelam Hydrochloride</td><td>496.125 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	Colesevelam HCL for oral suspension 3.75 GM (Per Pack 30 Pouches)((Net. Content of Colesevelam Hydrochloride is 472.50 kgs))	4200 Number Packs	1	Colesevelam Hydrochloride	496.125 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Colesevelam HCL for oral suspension 3.75 GM (Per Pack 30 Pouches)((Net. Content of Colesevelam Hydrochloride is 472.50 kgs))	4200 Number Packs	1	Colesevelam Hydrochloride	496.125 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	198 / NC/3/MEET/Mar/202223/22			
Case Status	Case Deferred			
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED			
Meeting Number	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023			

and Date	
HQ File Number	HQRNORM APPLY 00004258AM23
RA File Number	03AX04003990 AM23
Licence No and Date	0311019120/10/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	199 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	BOTANIC HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004273AM23
RA File Number	09AX04000641 AM23
Licence No and Date	0911003939/10/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	200 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004274AM23
RA File Number	05AX04002301 AM23
Licence No and Date	0511015737/10/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Department of Biotechnology (DBT) for obtaining their comments.	

Case No.	201 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004277AM23
RA File Number	05AX04002083 AM23
Licence No and Date	0511015742/10/11/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and it was decided to refer the case to Department of Biotechnology (DBT) for obtaining their comments.

Case No.	202 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004284AM23
RA File Number	04AX04000700 AM23
Licence No and Date	0411004428/11/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	203 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004292AM23
RA File Number	05AX04002111 AM23
Licence No and Date	0511015766/11/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Department of Biotechnology (DBT) for obtaining their comments.	

Case No.	204 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004332AM23
RA File Number	05AX04002253 AM23
Licence No and Date	0511015792/14/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and 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:	

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Amoxycillin Capsules 250 mg (Each capsule contains Amoxycillin Trihydrate equivalent to 250 mg of Amoxycillin)((Equivalent to 250.000Kg of bulk drug))	1000000 numbers	1	Amoxycillin Trihydrate	292.68 kg.
2	Amoxycillin Capsules 500 mg (Each capsule contains Amoxycillin Trihydrate equivalent to 500 mg of Amoxycillin)((Equivalent to 500.000 Kg of bulk drug))	1000000 numbers	2	Amoxycillin Trihydrate	585.36 kg
3	Amoxycillin Tablets 1000 mg (Each tablet contains Amoxycillin Trihydrate equivalent to 1000 mg of Amoxycillin)((Equivalent to 1000.000Kg of bulk drug))	1000000 numbers	3	Amoxycillin Trihydrate	1170.72 kg.
4	Export Item Name: Amoxycillin Trihydrate & Clavulanate Potassium + Microcrystalline Cellulose 1:1 Tablets/Capsules 375 mg (Each Tablet/Capsule contains to Amoxycillin 250mg & Clavulanate Potassium + Microcrystalline Amoxycillin Trihydrate equivalent Cellulose (1:1) equivalent to Clavulanic acid 125mg) (Equivalent to 2050.000Kg of Amoxycillin Trihydrate & 1025.000Kg of Clavulanate Po)	8200000 numbers	4	Amoxycillin Trihydrate	2399.64 kg.
			5	Clavulanate Potassium + Microcrystalline Cellulose (1:1)	2490.94 kg.
5	Amoxycillin Trihydrate and Clavulanate Potassium + Microcrystalline Cellulose 1:1 Tablets/Capsules 625 mg (Each Tablet/Capsule contains Amoxycillin Trihydrate equivalent to Amoxycillin 500mg and Clavulanate Potassium + Microcrystalline Cellulose (1:1) equivalent to Clavulanic acid 125mg) (Equivalent to 10500.000Kg of Amoxycillin Trihydrate and 2625.000Kg of Clavulanate)	21000000 numbers	6	Amoxycillin Trihydrate	12290.86 kg.
			7	Clavulanate Potassium + Microcrystalline Cellulose (1:1)	6379.23 kg.
6	Amoxycillin Trihydrate and Clavulanate Potassium + Microcrystalline Cellulose 1:1 Tablets/Capsules 1000 mg (Each Tablet/Capsule contains Amoxycillin Trihydrate equi. to Amoxycillin 875mg & Clavulanate Potassium + Microcrystalline Cellulose (1:1) equi. to Clavulanic acid 125mg) (Equi. to 20300.000Kg of Amoxycillin Trihydrate and 2900.000Kg of Clavulanate Potassium + M)	23200000	8	Amoxycillin Trihydrate	23762.32 kg.
			9	Clavulanate Potassium + Microcrystalline Cellulose (1:1)	7047.53 kg.

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

Case No.	205 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred

Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004335AM23
RA File Number	09AA04002473 AM22
Licence No and Date	0911003950/14/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	206 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004336AM23
RA File Number	05AX04002273 AM23
Licence No and Date	0511015796/14/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	207 / NC/3/MEET/Mar/202223/22			
Case Status	Case Approved			
Party Name	TADIMETY AROMATICS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023			
HQ File Number	HQRNORM APPLY 00004343AM23			
RA File Number	07AX04001143 AM23			
Licence No and Date	0711005697/14/11/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and 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:				

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

Case No.	208 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004383AM23
RA File Number	08AX04001342 AM23
Licence No and Date	0811006452/16/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	209 / NC/3/MEET/Mar/202223/22										
Case Status	Case Approved										
Party Name	BIOXERA PHARMA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023										
HQ File Number	HQRNORM APPLY 00004407AM23										
RA File Number	03AX04004117 AM23										
Licence No and Date	0311019279/17/11/2022										
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/Apr/202223/1 dated 29/04/2022 against advance authorization No. 0311009297 dated 08/12/2021 , 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:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>BENFOTIAMINE</td><td>1 kg</td><td>1</td><td>THIAMINE HYDROCHLORIDE</td><td>0.922 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	BENFOTIAMINE	1 kg	1	THIAMINE HYDROCHLORIDE	0.922 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
BENFOTIAMINE	1 kg	1	THIAMINE HYDROCHLORIDE	0.922 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	210 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004409AM23
RA File Number	03AX04003954 AM23
Licence No and Date	0311019281/17/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	211 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004411AM23
RA File Number	09AX04000695 AM23
Licence No and Date	0911003896/17/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	212 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ENVEE DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004428AM23
RA File Number	34AX04000741 AM23
Licence No and Date	3411003006/17/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	213 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004437AM23
RA File Number	03AX04003955 AM23
Licence No and Date	0311019320/18/11/2022
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	214 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004440AM23
RA File Number	03AX04004060 AM23
Licence No and Date	0311019325/18/11/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: Correct chemistry giving all the imported items to use and their molecular weight. End use of export product with yield of the reaction. Calculation for the requirement of input (both imported and indigenous) based on the chemistry and accordingly to fill indigenous item in Annexure to Appendix 4E.	

Case No.	215 / NC/3/MEET/Mar/202223/22													
Case Status	Case Approved													
Party Name	ATUL LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023													
HQ File Number	HQRNORM APPLY 00004441AM23													
RA File Number	08AX04001243 AM23													
Licence No and Date	0811006468/18/11/2022													
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/202122/4 dated 15/07/2021 against advance authorization No. 0811000725 dated 19-02-2021 , 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:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="2">Cresyl Glycidyl Ether</td><td rowspan="2">1 kg</td><td>1</td><td>Epichlorohydrin</td><td>0.626 kg</td></tr><tr><td>2</td><td>Ortho Cresol</td><td>0.725 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Cresyl Glycidyl Ether	1 kg	1	Epichlorohydrin	0.626 kg	2	Ortho Cresol	0.725 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Cresyl Glycidyl Ether	1 kg	1	Epichlorohydrin	0.626 kg										
		2	Ortho Cresol	0.725 kg										

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

Case No.	216 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004443AM23
RA File Number	34AX04000759 AM23
Licence No and Date	3411003012/18/11/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm i. Complete chemical reactions and molecular weights along with stage wise percentage yields on molar basis. ii. Requirement and recovery of solvent at each step.	

Case No.	217 / NC/3/MEET/Mar/202223/22									
Case Status	Case Approved									
Party Name	UNIMAX CHEMICALS PRIVATE LIMITED									
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023									
HQ File Number	HQRNORM APPLY 00004457AM23									
RA File Number	03AX04003285 AM23									
Licence No and Date	0311019353/18/11/2022									
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/Nov/202223/14 dated 07/12/2022 against advance authorization No. 0311006660 dated 03/09/2021 , 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:										
<table><tr><td>Sl. No.</td><td>Export Product</td><td>SION No.</td></tr><tr><td>1</td><td>Erythromycin Base/Erythromycin</td><td>A-215</td></tr><tr><td>2</td><td>Erythromycin Oxime Base (Erythromycin A-9 Oxime)</td><td>A-2244</td></tr></table>		Sl. No.	Export Product	SION No.	1	Erythromycin Base/Erythromycin	A-215	2	Erythromycin Oxime Base (Erythromycin A-9 Oxime)	A-2244
Sl. No.	Export Product	SION No.								
1	Erythromycin Base/Erythromycin	A-215								
2	Erythromycin Oxime Base (Erythromycin A-9 Oxime)	A-2244								

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

Case No.	218 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004460AM23
RA File Number	08AX04001323 AM23
Licence No and Date	0811006485/18/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to ratify adhoc norms as per SION A-412.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	219 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004468AM23
RA File Number	34AX04000711 AM23
Licence No and Date	3411003022/18/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	220 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004503AM23
RA File Number	09AX04000712 AM23
Licence No and Date	0911003988/21/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Department of Bio Technology	

(DBT) for obtaining their comments.

Case No.	221 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004509AM23
RA File Number	09AX04000587 AM23
Licence No and Date	0911003994/21/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	222 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004510AM23
RA File Number	04AX04000675 AM23
Licence No and Date	0411004400/21/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	223 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004512AM23
RA File Number	09AX04000684 AM23
Licence No and Date	0911003996/21/11/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Department of Bio Technology (DBT) for obtaining their comments.	

Case No.	224 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ASSOCIATED DYESTUFF PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004521AM23
RA File Number	08AX04001207 AM23
Licence No and Date	0811006504/22/11/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: i. Chemistry starting from Acetanilide to formation of end product giving molecular weight of all the reactant and product. ii. Yield of reaction and reason for low yield, if any. iii. End use of Export product.	

Case No.	225 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004522AM23
RA File Number	08AX04001395 AM23
Licence No and Date	0811006510/22/11/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	226 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004528AM23
RA File Number	03AX04003867 AM23
Licence No and Date	0311019424/22/11/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	227 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved

Party Name	PANACEA BIOTEC LIMITED																						
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023																						
HQ File Number	HQRNORM APPLY 00004540AM23																						
RA File Number	05AX04002454 AM23																						
Licence No and Date	0511015958/22/11/2022																						
Norms Committee Decision: The Committee considered the case as per agenda and on the basis of written comments furnished by Department of Biotechnology vide its D.O. Letter No. PID-13011(15)/1/2021-PPB-DBT dated 28.02.2023 for similar case of the firm, 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: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="4"> BIVALENT (Type 1 & Type 3) ORAL POLIOMYELITIS VACCINE (bOPV), 20 DOSE VIAL -(Live Oral Sabin Strain, Bivalent, Ready for use in vials of 20 doses with droppers, with vaccine vial monitor (VVM) affixed on the individual vial)) </td> <td rowspan="4">1,00,000 Vials</td> <td>1</td> <td>Monovalent Bulk of Poliomyelitis Type 1</td> <td>14.23 Litres</td> </tr> <tr> <td>2</td> <td>Monovalent Bulk of Poliomyelitis Type 3</td> <td>8.98 Litres</td> </tr> <tr> <td>3</td> <td>Rubber Stopper</td> <td>1,02,000 Numbers</td> </tr> <tr> <td>4</td> <td>VVM DOT for OPV</td> <td>1,02,000 Numbers</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.	BIVALENT (Type 1 & Type 3) ORAL POLIOMYELITIS VACCINE (bOPV), 20 DOSE VIAL -(Live Oral Sabin Strain, Bivalent, Ready for use in vials of 20 doses with droppers, with vaccine vial monitor (VVM) affixed on the individual vial))	1,00,000 Vials	1	Monovalent Bulk of Poliomyelitis Type 1	14.23 Litres	2	Monovalent Bulk of Poliomyelitis Type 3	8.98 Litres	3	Rubber Stopper	1,02,000 Numbers	4	VVM DOT for OPV	1,02,000 Numbers
Export product	Qty.	Sl. No.	Import items	Qty.																			
BIVALENT (Type 1 & Type 3) ORAL POLIOMYELITIS VACCINE (bOPV), 20 DOSE VIAL -(Live Oral Sabin Strain, Bivalent, Ready for use in vials of 20 doses with droppers, with vaccine vial monitor (VVM) affixed on the individual vial))	1,00,000 Vials	1	Monovalent Bulk of Poliomyelitis Type 1	14.23 Litres																			
		2	Monovalent Bulk of Poliomyelitis Type 3	8.98 Litres																			
		3	Rubber Stopper	1,02,000 Numbers																			
		4	VVM DOT for OPV	1,02,000 Numbers																			

Case No.	228 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004554AM23
RA File Number	05AX04002424 AM23
Licence No and Date	0511015979/23/11/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	229 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred

Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004555AM23
RA File Number	09AX04000691 AM23
Licence No and Date	0911004009/23/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	230 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004556AM23
RA File Number	09AX04000632 AM23
Licence No and Date	0911004008/23/11/2022

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/Jan/202223/18 dated 23/01/2023** against advance authorization No. **0911003627 dated 15/09/2022**, 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.
LINEZOLID	1 kg	1	3,4-Difluoro Nitrobenzene	0.80 kg
		2	(S)-(+)-Epichlorohydrin (OR) (s)-(+)-2-(Chloromethyl) Oxirane	0.80 kg
		3	Triethyl Amine	0.20 kg
		4	Ethyl Acetate	2.50 kg
		5	Isopropyl Alcohol (IPA)	2.00 kg
		6	Hydrazine Hydrate	1.00 kg
		7	Methylene Di Chloride (MDC)	0.80 kg

		8	Methanol	1.50 kg
--	--	---	----------	---------

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

Case No.	231 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004563AM23
RA File Number	03AX04004200 AM23
Licence No and Date	0311019475/24/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	232 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004568AM23
RA File Number	03AX04004067 AM23
Licence No and Date	0311019482/24/11/2022

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/202223/9 dated 07/10/2022** against advance authorization No. **0311012325 dated 07/03/2022**, 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:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Benzocaine and Cetylpyridinium Chloride Anaesthetic Throat Lozenges. Flavours Black Current, Honey Lemon & Other Flavour(Each Lozenge Contains 12mg Benzocaine. Net content of Benzocaine - 90.323 Kgs.)	1 Number	1	Benzocaine	12.24 mg

2	Benzocaine and Cetylpyridinium Chloride Anaesthetic Throat Lozenges. Flavours Black Current and Lime & Lemon and Other (Flavours. Each Lozenge contains 10mg Benzocaine. Net content of Benzocaine - 20.339 Kgs.)	1 Number	2	Benzocaine	10.20 mg
3	Benzocaine, Cetylpyridinium Chloride And Dextromethorphan Hydrobromide Anaesthetic Throat Lozenges.(Each Lozenge Contains 1.25mg Benzocaine. Net content of Benzocaine - 2.367 Kgs.)	1 Number	3	Benzocaine	1.275 mg
4	Life Brand Sore Throat & Nasal Congestion Relief Extra Strength (Flavours Cherry/Honey & Lemon/Other flavours) (Sugar Free Lozenges. Each Lozenge Contains Benzocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 9.934 Kgs and Isomalt ST-M - 1702.742 Kgs.)	1 Number	4	Benzocaine	15.30 mg
			5	Isomalt ST-M	2571.00 mg
5	Personnelle Oral Anesthetic Sore Throat Lozenges Extra Strenght Sugar Free (Flavours Cherry/Honey Lemon/Other flavours) (Each Lozenge Contains Benzocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 9.934 Kgs and Isomalt ST-M - 1702.742 Kgs.)	1 Number	6	Benzocaine	15.30 mg
			7	Isomalt ST-M	2571.00 mg
6	Option+Oral Lozenges Sore Throat & Nasal Congestion Relief Extra Strenght (Flavours Cherry/Honey Lemon /Other flavours).(Each Lozenge Contains Benzocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 9.934 Kgs and Isomalt ST-M - 1702.742 Kgs.)	1 Number	8	Benzocaine	15.30 mg
			9	Isomalt ST-M	2571.00 mg
7	Biomedic Oral Anesthetic Lozenges Sore Throat & Nasal Congestion Relief Extra Strength Cherry ST & NC RELEX (Lozenges (Flavours Cherry / Honey Lemon/ Other flavours) Each Lozenge Contains Benzocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 9.934 Kgs and Isomalt ST-M - 1702.742 Kgs.)	1 Number	10	Benzocaine	15.30 mg
			11	Isomalt ST-M	2571.00 mg

8	Atoma Sore Throat & Nasal Congestion Relief Extra Strength Lozenges Cherry/Honey & Lemon Flavour. (Each Lozenge Contains Benzocaine 15 mg & Isomalt ST-M 2700 Mg. Net Content Benzocaine 6.623 Kgs and Isomalt ST-M - 1135.148 Kgs.)	1 Number	12	Benzocaine	15.30 mg
			13	Isomalt ST-M	2700.00 mg

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

Case No.	233 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004570AM23
RA File Number	03AX04003803 AM23
Licence No and Date	0311019484/24/11/2022

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/May/202223/4 dated 17/06/2022** against advance authorization No. **0311004497 dated 10/06/2021**, 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:

Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	GLIPIZIDE EXTENDED RELEASE TABLETS 10 MG. Each tablet contains (i) Glipizide USP- 10 mg(ii) Eastman (TM) Cellulose Acetate (CA 398-10NF/EP)- 29.70 mg (iii) Sentry Polyox WSR N80 FP NF- 178.10 mg (iv) Sentry Polyox WSR 303 NF- 100 mg. Net content (i) 317.12 Kgs (ii) 941.84 Kgs (iii) 5647.85 Kgs (iv) 3171.17 Kgs.)	1 Number	1	GLIPIZIDE USP	10.20 mg
			2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	29.70 mg
			3	SENTRY POLYOX WSR N80 FP NF	178.10 mg
			4	SENTRY POLYOX WSR 303 NF	100.00 mg
			5	GLIPIZIDE USP	5.10 mg

2	GLIPIZIDE EXTENDED RELEASE TABLETS 5 MG. Each tablet contains (i) Glipizide USP- 5 mg((ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 20.40 mg (iii) Sentry Polyox WSR N80 FP NF- 89.05 mg (iv) Sentry Polyox WSR 303 NF- 50 mg. Net content (i) 256.76 Kgs (ii) 1047.57 Kgs (iii) 4572.84 Kgs (iv) 2567.57 Kgs.)	1 Number	6	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	20.40 mg
			7	SENTRY POLYOX WSR N80 FP NF	89.05 mg
			8	SENTRY POLYOX WSR 303 NF	50.00 mg
3	GLIPIZIDE EXTENDED RELEASE TABLETS 2.5 MG. Each tablet contains (i) Glipizide USP- 2.5 mg((ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 20.40 mg (iii) Sentry Polyox WSR N80 FP NF- 89.05 mg (iv) Sentry Polyox WSR 303 NF- 50 mg. Net content (i) 101.80 Kgs (ii) 830.70 Kgs (iii) 3626.18 Kgs (iv) 2036.04 Kgs.)	1 Number	9	GLIPIZIDE USP	2.55 mg
			10	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	20.40 mg
			11	SENTRY POLYOX WSR N80 FP NF	89.05 mg
			12	SENTRY POLYOX WSR 303 NF	50.00 mg

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

Case No.	234 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004571AM23
RA File Number	03AX04003604 AM23
Licence No and Date	0311019487/24/11/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to ratify ad-hoc norms as per following products:-

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

Ciprofloxacin Hydrochloride USP	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg

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

Case No.	235 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004575AM23
RA File Number	31AX04000236 AM23
Licence No and Date	3111001838/24/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	236 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	NICHINO INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004577AM23
RA File Number	09AX04000753 AM23
Licence No and Date	0911004012/24/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	237 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	ENALTEC LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004589AM23
RA File Number	03AX04004127 AM23
Licence No and Date	0311019499/24/11/2022

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/202122/2 dated 02/07/2021** against advance authorization No. **0311002347 dated 05-04-2021**, 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.
Oxcarbazepine USP	1 kg	1	10-Methoxy Iminostilbene	1.10 kg

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

Case No.	238 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	VIRCHOW DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004590AM23
RA File Number	09AX04000666 AM23
Licence No and Date	0911004017/24/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	239 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004603AM23
RA File Number	03AX04004186 AM23
Licence No and Date	0311019528/25/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	240 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	NICHINO INDIA PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004625AM23
RA File Number	09AX04000754 AM23
Licence No and Date	0911004025/28/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	241 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004626AM23
RA File Number	03AX04004277 AM23
Licence No and Date	0311019549/28/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	242 / NC/3/MEET/Mar/202223/22										
Case Status	Case Approved										
Party Name	ENALTEC LABS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023										
HQ File Number	HQRNORM APPLY 00004627AM23										
RA File Number	03AX04004133 AM23										
Licence No and Date	0311019550/28/11/2022										
Norms Committee Decision:											
The Committee considered the request of firm for fixation of adhoc norms and 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:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Sitagliptin Phosphate Monohydrate</td><td>1 Kg.</td><td>1</td><td>(3R)-3-AMINO-1-[3-TRIFLUOROMETHYL)-5,6,7,8-TETRAHYDRO-12,4TRIAZOLO [4,3-a]PYRAZIN-7-YL]-4- (2,4,5-TRIFLUOROPHENYL)BUTAN -1-one</td><td>0.934 kg.</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Sitagliptin Phosphate Monohydrate	1 Kg.	1	(3R)-3-AMINO-1-[3-TRIFLUOROMETHYL)-5,6,7,8-TETRAHYDRO-12,4TRIAZOLO [4,3-a]PYRAZIN-7-YL]-4- (2,4,5-TRIFLUOROPHENYL)BUTAN -1-one	0.934 kg.
Export product	Qty.	Sl. No.	Import items	Qty.							
Sitagliptin Phosphate Monohydrate	1 Kg.	1	(3R)-3-AMINO-1-[3-TRIFLUOROMETHYL)-5,6,7,8-TETRAHYDRO-12,4TRIAZOLO [4,3-a]PYRAZIN-7-YL]-4- (2,4,5-TRIFLUOROPHENYL)BUTAN -1-one	0.934 kg.							

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

Case No.	243 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004628AM23
RA File Number	03AX04004211 AM23
Licence No and Date	0311019551/28/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	244 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004629AM23
RA File Number	03AX04004039 AM23
Licence No and Date	0311019553/28/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	245 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004630AM23
RA File Number	03AX04004100 AM23
Licence No and Date	0311019554/28/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	246 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	COVALENT LABORATORIES PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023

and Date																							
HQ File Number	HQRNORM APPLY 00004635AM23																						
RA File Number	09AX04000756 AM23																						
Licence No and Date	0911004029/28/11/2022																						
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/NOV/202223/12 dated 18.11.2022 against advance authorization No. 0911002806 dated 30.03.2022, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol.1 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.</th> </tr> </thead> <tbody> <tr> <td rowspan="4">Ceftriaxone Sodium Sterile (PKD 10 KG IN 20LTRS)(API)</td> <td rowspan="4">1 kg.</td> <td>1</td> <td>Ceftriaxone Sodium Non Sterile</td> <td>1.04 kg.</td> </tr> <tr> <td>2</td> <td>Acetone</td> <td>1.72 kg.</td> </tr> <tr> <td>3</td> <td>Activated Carbon [Carbon Enoanticromos]</td> <td>51.66 gram</td> </tr> <tr> <td>4</td> <td>Aluminium Canisters 20L with inner & Outer Lids</td> <td>Relevant as per packing policy with accountability</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.	Ceftriaxone Sodium Sterile (PKD 10 KG IN 20LTRS)(API)	1 kg.	1	Ceftriaxone Sodium Non Sterile	1.04 kg.	2	Acetone	1.72 kg.	3	Activated Carbon [Carbon Enoanticromos]	51.66 gram	4	Aluminium Canisters 20L with inner & Outer Lids	Relevant as per packing policy with accountability
Export product	Qty.	Sl. No.	Import items	Qty.																			
Ceftriaxone Sodium Sterile (PKD 10 KG IN 20LTRS)(API)	1 kg.	1	Ceftriaxone Sodium Non Sterile	1.04 kg.																			
		2	Acetone	1.72 kg.																			
		3	Activated Carbon [Carbon Enoanticromos]	51.66 gram																			
		4	Aluminium Canisters 20L with inner & Outer Lids	Relevant as per packing policy with accountability																			

Case No.	247 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	COVALENT LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004636AM23
RA File Number	09AX04000755 AM23
Licence No and Date	0911004030/28/11/2022
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/NOV/202223/12 dated 18.11.2022 against advance authorization No. 0911002806 dated 30.03.2022, it was decided to ratify adhoc 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.
Ceftriaxone Sodium Sterile (PKD 10 KG IN 20LTRS)(API)	1 kg.	1	Ceftriaxone Sodium Non Sterile	1.04 kg.
		2	Acetone	1.72 kg.
		3	Activated Carbon [Carbon Enoanticromos]	51.66 gram
		4	Aluminium Canisters 20L with inner & Outer Lids	Relevant as per packing policy with accountability

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

Case No.	248 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004638AM23
RA File Number	31AX04000235 AM23
Licence No and Date	3111001845/28/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	249 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004644AM23
RA File Number	09AX04000725 AM23
Licence No and Date	0911004033/28/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	250 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred

Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004648AM23
RA File Number	09AX04000768 AM23
Licence No and Date	0911004035/28/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	251 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004663AM23
RA File Number	03AX04004308 AM23
Licence No and Date	0311019588/29/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	252 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004666AM23
RA File Number	08AX04001437 AM23
Licence No and Date	0811006586/29/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	253 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004668AM23
RA File Number	31AX04000250 AM23
Licence No and Date	3111001849/29/11/2022

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/Oct/202223/11 dated 31/10/2022** against advance authorization No. **3111000824 dated 22/12/2021**, 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.
ETHYLENEDIAMINE (ORGANIC CHEMICAL)	1 kg	1	MONO ETHANOL AMINE	1.0374 kg
		2	AMMONIA ANHYDROUS	Not allowed, as it is shown indigenous

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

Case No.	254 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004671AM23
RA File Number	34AX04000782 AM23
Licence No and Date	3411003042/29/11/2022

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/Jan/202223/18 dated 23/01/2023** against advance authorization No. **3411002686 dated 26/08/2022**, 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.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	255 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004680AM23
RA File Number	05AX04002461 AM23
Licence No and Date	0511016086/29/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	256 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004687AM23
RA File Number	09AX04000763 AM23
Licence No and Date	0911004042/29/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	257 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004688AM23
RA File Number	09AX04000724 AM23
Licence No and Date	0911004047/29/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	258 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004689AM23

RA File Number	08AX04001385 AM23
Licence No and Date	0811006590/29/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	259 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004690AM23
RA File Number	34AX04000779 AM23
Licence No and Date	3411003057/29/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	260 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004723AM23
RA File Number	09AX04000639 AM23
Licence No and Date	0911004062/30/11/2022
Norms Committee Decision:	
Deferred for comments of TE	

Case No.	261 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004725AM23
RA File Number	09AX04000586 AM23
Licence No and Date	0911004061/30/11/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	262 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
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 it was decided to call for following information/documents from the firm: Complete chemistry giving calculation based on molecular weight of reactant and product. Stage-wise yield of the reaction. Indicate molecular weight of export item PDSH and its end use.	

Case No.	263 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004728AM23
RA File Number	03AX04004201 AM23
Licence No and Date	0311019658/01/12/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	264 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004731AM23
RA File Number	09AX04000744 AM23
Licence No and Date	0911004065/01/12/2022
Norms Committee Decision: Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jan/202223/18 dated 23.01.2023 against advance authorization	

No. **0911003684 dated 23.09.2022**, it was decided to ratify adhoc 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.
sodium (S)-4-oxo-4,6,7,8-tetrahydropyrrolo [1,2-a]pyrimidine-6-carboxylate((Pyrimidinone acid, sodium salt))	1 kg	1	L Pyroglutamic Acid	2.70 kg
		2	Triethyl Amine	2.27 kg
		3	2,5-Norbornadiene	1.73 kg
		4	Chloro Sulfonyl Isocyanate	2.778 kg
		5	Isopropyl Alcohol	4.02 kg
		6	Methyl Tert Butyl Ether	5.91 kg
		7	Toluene	5.72 Litre
		8	Ethyl Acetate	2.95 Litre
		9	N-Heptane	1.82 kg
		10	Ethyl Benzene	1.00 kg
		11	Methanol	1.50 kg
		12	Methylene Chloride	3.25 Litre

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

Case No.	265 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004736AM23

RA File Number	03AX04004272 AM23			
Licence No and Date	0311019669/01/12/2022			
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/Jun/202223/5 dated 08.07.2022 against advance authorization No. 0311002238 dated 05.03.2021 , it was decided to ratify adhoc 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.
Levetiracetam USP / BP / EP	1 kg	1	(S)-2-amino butyramide hydrochloride (SABA)	0.95 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	266 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004745AM23
RA File Number	04AX04000794 AM23
Licence No and Date	0411004556/01/12/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	267 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004759AM23
RA File Number	08AX04001392 AM23
Licence No and Date	0811006651/02/12/2022
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/Jan/202223/18 dated 23/01/2023 against advance authorization No.	

0811002280 dated 09/08/2021, 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.
NALTREXONE HYDROCHLORIDE TABLETS USP 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE USP 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 901.455 KGS.])	1 Number	1	NALTREXONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR (All Alcoholic Solvents and water content NLT 1.86% as per COA of import item)	51.93 mg / Tablet

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

Case No.	268 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	REYAANSH HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004769AM23
RA File Number	03AX04004317 AM23
Licence No and Date	0311019713/02/12/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	269 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004771AM23
RA File Number	03AX04004397 AM23
Licence No and Date	0311019716/02/12/2022
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	270 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004775AM23
RA File Number	08AX04001465 AM23
Licence No and Date	0811006658/02/12/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to ratify adhoc norms as per SION A-412. RA concerned may take further necessary action as per above decision of NC.	

Case No.	271 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004788AM23
RA File Number	03AX04004005 AM23
Licence No and Date	0311019730/02/12/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	272 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004797AM23
RA File Number	03AX04004271 AM23
Licence No and Date	0311019736/03/12/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to ratify adhoc norms as per SION A-412.	

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

Case No.	273 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004798AM23
RA File Number	03AX04004191 AM23
Licence No and Date	0311019737/03/12/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	274 / NC/3/MEET/Mar/202223/22													
Case Status	Case Approved													
Party Name	INDO AMINES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023													
HQ File Number	HQRNORM APPLY 00004800AM23													
RA File Number	03AX04004219 AM23													
Licence No and Date	0311019745/05/12/2022													
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/Dec/202223/17 dated 13/01/2023 against advance authorization No. 0311016801 dated 02/08/2022 , 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:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>SORBITAN MONO OLEATE OR IAL SMO</td><td>1 kg</td><td>1</td><td>Sorbitol 70 %</td><td>0.425 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	SORBITAN MONO OLEATE OR IAL SMO	1 kg	1	Sorbitol 70 %	0.425 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
SORBITAN MONO OLEATE OR IAL SMO	1 kg	1	Sorbitol 70 %	0.425 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	275 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	ADCOCK INGRAM LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023			
HQ File Number	HQRNORM APPLY 00004805AM23			
RA File Number	07AX04001268 AM23			
Licence No and Date	0711005862/05/12/2022			
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. 15/82-ALC4/2018 dated 22/03/2019 against advance authorization 0710108278 dated 27/05/2015 , it was decided to ratify ad-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.
Neulin 125mg Tablets - Theophylline 125 Mg +Guar gum 4.375 Mg (9142857 No. of Tabs) (Theop-1142.857 +GUAR.GUM 40.000 KGS)	1 no. of Tablet	1.	Theophylline BP / EP / USP / PH.EUR Anhydrous Powder	127.5 mg
		2.	Guar Gum IH (BP / EP / USP / PH.EUR)	4.375 mg
Neulin 200mg Tablets - Theophylline 200 Mg + Guar gum 7.00 Mg(9142857 No. of Tabs) (Theop-1828.571+GUAR.GUM 64.000 KGS)	1 no. of tablet	1	Theophylline BP / EP / USP / PH.EUR Anhydrous Powder	204.0 mg
		2	Guar Gum IH (BP / EP / USP / PH.EUR)	7.00 mg
Neulin 250mg Tablets - Theophylline 250 Mg + Guar gum 8.750 Mg (9142857 No. of Tabs) (Theop-2285.714+GUAR.GUM 80.000 KGS)	1 no. of tablet	1	Theophylline BP / EP / USP / PH.EUR Anhydrous Powder	255.0 mg
		2	Guar Gum IH (BP / EP / USP / PH.EUR)	8.75 mg
Neulin 300mg Tablets - Theophylline 300 Mg + Guar gum 10.5 Mg (9142857 No. of Tabs) (Theop-2742.857+GUAR.GUM 96.000 KGS)	1 no. of tablet	1	Theophylline BP / EP / USP / PH.EUR Anhydrous Powder	306.0 mg
		2	Guar Gum IH (BP / EP / USP / PH.EUR)	10.5 mg

RA may take appropriate action as per the decision of Norms Committee.

Case No.	276 / NC/3/MEET/Mar/202223/22
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004806AM23
RA File Number	26AX04000073 AM23
Licence No and Date	2611000779/05/12/2022

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/Feb/202223/20 dated 24/02/2023** against advance authorization **No.2611000569 dated 02/05/2022**, it was decided to ratify ad-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.
Tamoxifen 20 mg (Each uncoated tablets contains: Tamoxifen Citrate Equivalent to Tamoxifen 20 mg)	1 Number	1	Tamoxifen citrate	30.4 mg
		2	Calcium hydrogen phosphate dihydrate	281.6 mg
		3	Povidone K 25	8.00 mg
		4	Sodium starch glycolate, type A	20.00 mg
		5	Magnesium stearate	5.00 mg
		6	Cellulose, microcrystalline	33.00 mg
		7	Silica, colloidal anhydrous	2.00 mg

RA may take appropriate action as per the decision of Norms Committee.

Case No.	277 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004807AM23

RA File Number	03AX04004440 AM23
Licence No and Date	0311019755/05/12/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	278 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	RAVOO'S LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004812AM23
RA File Number	09AX04000761 AM23
Licence No and Date	0911004086/05/12/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	279 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004828AM23
RA File Number	09AX04000798 AM23
Licence No and Date	0911004095/06/12/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	280 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	SHIVA BIO CHEM INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004832AM23
RA File Number	50AX04000071 AM23
Licence No and Date	5011000702/06/12/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm to attend <u>Personal Hearing</u> before Norms Committee to explain its case.	

Case No.	281 / NC/3/MEET/Mar/202223/22
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Mar/ 202223/ 22 and 24/03/2023
HQ File Number	HQRNORM APPLY 00004836AM23
RA File Number	03AX04004351 AM23
Licence No and Date	0311019783/06/12/2022
Norms Committee Decision:	
Deferred for comments of TE.	