



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/Apr/202324/1**DATED:** 28/04/2023Please 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/Apr/202324/1 dated 28/04/2023 of Norms Committee - III for the year 2023-24 was held on 28/04/2023 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	T SONGZALIAN, Deputy DGFT	DGFT(HQ)
2	UTTAM SARKAR, Assistant Section Officer	DGFT(HQ)
3	NAND Lal, Technical Consultant	DPIIT
4	SHAISH KUMAR, Technical Consultant	DGFT
5	DINESHNARAIN MATHUR, Technical Consultant	DGFT
6	Nand Lal, Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00004822AM23
RA File Number	039404001053 AM18
Licence No and Date	0310819947/20/03/2018

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
PARA TERTIARY BUTYL CYCLOHEXYL ACETATE - SUPER	1 kg.	1	PARA TERTIARY BUTYL PHENOL	0.820 kg.
		2	5% RHODIUM ON ALUMINA CATALYST	0.00012 kg.
		3	ACETIC ACID	0.300 kg

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

Case No.	2 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00006806AM23
RA File Number	318304000162 AM19
Licence No and Date	3110067309/06/02/2019

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to ratify ad-

ad-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.
DNOVO BP818 (Tetra Methyl Bisphenol F)	1 MT	1	2,6 xyleneol	1.06 MT
		2	Paraformaldehyde	0.1302 MT
		3	Methanol	0.10 MT

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

Case No.	3 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	CONCORD BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00004550AM23
RA File Number	082404000101 AM20
Licence No and Date	0810145581/27/06/2019

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms and 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.
Everolimus Premix 2%	1 kg.	1	Sirolimus crude	267 gm.
Everolimus Premix 9.09%	1 kg.	1	Sirolimus crude	1211 gm

The ad-hoc has been fixed with following conditions:

1. The firm has changed the export item as above.
2. The firm is advised to get their Advance Authorization amended for above export items for which the norms have been fixed by Norms Committee.

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

Case No.	4 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00004154AM23
RA File Number	039404000526 AM20
Licence No and Date	0310832396/23/10/2019
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	5 / NC/3/MEET/Apr/202324/1													
Case Status	Case Approved													
Party Name	SRF LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023													
HQ File Number	HQRNORM REVIW00007268AM23													
RA File Number	052404000501 AM20													
Licence No and Date	0510412619/25/11/2019													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>2,2-difluoro-1,3-benzodioxole</td><td>1 Kg.</td><td>1</td><td>1,3-Benzodioxole (1,2- Methylenedioxybenzene)</td><td>0.9306 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	2,2-difluoro-1,3-benzodioxole	1 Kg.	1	1,3-Benzodioxole (1,2- Methylenedioxybenzene)	0.9306 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
2,2-difluoro-1,3-benzodioxole	1 Kg.	1	1,3-Benzodioxole (1,2- Methylenedioxybenzene)	0.9306 kg.										

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

Case No.	6 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	ARENE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00004461AM23
RA File Number	092404000024 AM21
Licence No and Date	0910068681/28/04/2020
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm: -	
1. Production and consumption data with respect to present Advance Authorisation duly certified by Central Taxes and GST Authorities. 2. Also submit shipping bill and bill of entry of the export products.	

Case No.	7 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00007266AM23
RA File Number	052404000225 AM21
Licence No and Date	0510414951/20/08/2020
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	8 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	SHARP MINT LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00004537AM23
RA File Number	052404000265 AM21
Licence No and Date	0510415091/02/09/2020
Norms Committee Decision:	

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

- 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.
- vi. Also submit shipping bill and bill of entry of the export products.

Case No.	9 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00007269AM23
RA File Number	052404000333 AM21
Licence No and Date	0510415443/08/10/2020

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
2,2-difluoro-1,3-benzodioxole(DFBD)	1 Kg.	1	1,3-BENZODIOXOLE	0.9306 kg.
		2	BENZOTRIFLUORIDE (BTF)	0.15 kg.

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

Case No.	10 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00004313AM23
RA File Number	052404000355 AM21

Licence No and Date	0510415575/20/10/2020				
Norms Committee Decision:					
The Committee considered the request of firm for fixation of ad-hoc norms and 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.
Deferoxamine Mesylate Sterile		1 kg.	1	Deferoxamine Mesylate USP (non-sterile)	1.02 kg.
RA concerned may take further necessary action as per above decision of NC.					

Case No.	11 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00004138AM23
RA File Number	092404000365 AM21
Licence No and Date	0910069368/22/10/2020
Norms Committee Decision:	
Deferred for the comments of TE.Also submit shipping bill and bill of entry of the export products.	

Case No.	12 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00004153AM23
RA File Number	039404000571 AM21
Licence No and Date	0310839148/27/10/2020
Norms Committee Decision:	
Deferred for the comments of TE.Also submit shipping bill and bill of entry of the export products.	

Case No.	13 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00007267AM23
RA File Number	052404000395 AM21
Licence No and Date	0510415782/09/11/2020
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	14 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	AVA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00004365AM23
RA File Number	03AA04020902 AM21
Licence No and Date	0311001331/28/01/2021
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	15 / NC/3/MEET/Apr/202324/1			
Case Status	Case Approved			
Party Name	BEST VALUE CHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023			
HQ File Number	HQRNORM REVIW00004494AM23			
RA File Number	34AA04002284 AM21			
Licence No and Date	3411000167/29/01/2021			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and based on information provided by the firm, it was decided to revise ad-hoc norms as under: -				

Hydroxy Benzoate))				
		2	Salicylic Acid	0.682 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	16 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00005060AM23
RA File Number	07AA04002414 AM22
Licence No and Date	0711000982/27/04/2021

Norms Committee Decision:

The Committee considered the request of firm for fixation of ad-hoc norms and 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.
L-ORNITHINE-L-ASPARTATE (Pure-pharma) (L-ORNITHINE-L-ASPARTATE (Pure-pharma))	2.0 MT	1	L-ORNITHINE-L-ASPARTATE (TECHNICAL GRADE)	2.02 MT

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

Case No.	17 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	MEHK CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00004318AM23
RA File Number	03AA04061020 AM22
Licence No and Date	0311006197/16/08/2021

Norms Committee Decision:

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

- I. Justification of about 23% losses from Crude Fracton to Pure Fractone based on purity of export and COA of export product.**
- II. Production / Consumption data duly certified by GST.**
- III. Also submit shipping bill and bill of entry of the export products.**

Case No.	18 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00007301AM23
RA File Number	05AA04061713 AM22
Licence No and Date	0511004657/10/09/2021
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	19 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	AMINES AND PLASTICIZERS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM REVIW00004678AM23
RA File Number	03AA040113998 AM22
Licence No and Date	0311008443/11/11/2021
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. Complete calculation based on chemistry using MMEA-40% & Ethylene Oxide. 2. Production/Consumption Data duly certified by GST/CA. 3. Yield of reaction with justification and to give complete Stoichiometric material balance. 4. Also submit shipping bill and bill of entry of the export products.	

Case No.	20 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023

and Date																							
HQ File Number	HQRNORM REVIW00006236AM23																						
RA File Number	31AX04000028 AM23																						
Licence No and Date	3111001358/17/05/2022																						
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: -																							
<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">DNOVO BP818 (Tetra Methyl Bisphenol F)</td> <td rowspan="4">1 Kg.</td> <td>1</td> <td>OCP 50</td> <td>1.00 kg.</td> </tr> <tr> <td>2</td> <td>Paraformaldehyde</td> <td>0.141 kg.</td> </tr> <tr> <td>3</td> <td>Methanol</td> <td>0.66 kg.</td> </tr> <tr> <td>4</td> <td>Katalco 71 5</td> <td>0.004 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	DNOVO BP818 (Tetra Methyl Bisphenol F)	1 Kg.	1	OCP 50	1.00 kg.	2	Paraformaldehyde	0.141 kg.	3	Methanol	0.66 kg.	4	Katalco 71 5	0.004 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.																			
DNOVO BP818 (Tetra Methyl Bisphenol F)	1 Kg.	1	OCP 50	1.00 kg.																			
		2	Paraformaldehyde	0.141 kg.																			
		3	Methanol	0.66 kg.																			
		4	Katalco 71 5	0.004 kg.																			
RA concerned may take further necessary action as per the above decision of NC.																							

Case No.	21 / NC/3/MEET/Apr/202324/1								
Case Status	Case Approved								
Party Name	BIOXERA PHARMA PRIVATE LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023								
HQ File Number	HQRNORM APPLY 00004824AM23								
RA File Number	03AX04004276 AM23								
Licence No and Date	0311019771/06/12/2022								
Norms Committee Decision:									
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No. 0311019279 dated 17/11/2022, 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.									
<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.					

BENFOTIAMINE(BENFOTIAMINE)	1 kg	1	THIAMINE HYDROCHLORIDE	0.922 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	22 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004851AM23
RA File Number	04AX04000768 AM23
Licence No and Date	0411004581/07/12/2022

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.
IBUPROFEN	1 kg.	1	Isobutyl Acetophenone	1.11 kg.
		2	Sodium Metal	0.235 kg.
		3	Monochloro Acetic Acid	0.919 kg.
		4	Isopropyl Alcohol	0.50 kg.
		5	Sodium Dichromate	0.630 kg.

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

Case No.	23 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	NATCO PHARMA LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004859AM23
RA File Number	09AX04000769 AM23
Licence No and Date	0911004106/07/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Dec/202223/17 dated 13/01/2023** against advance authorization **No.0911002121 dated 21/12/2021**, 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.
NITROGLYCERIN SUBLINGUAL TABLETS USP 0.3 mg (Each Tablet contains Nitroglycerin USP 0.3 mg) (1x1,80,000=1,80,000 Tablets)	1 Number	1	DILUTED NITROGLYCERIN USP 1.95 %	15.70 mg.
		2	Glyceryl Monosterate (Imwitor 491 powder)	1.255 mg.
NITROGLYCERIN SUBLINGUAL TABLETS USP 0.4mg (Each Tablet contains Nitroglycerin USP 0.4mg) (2x12,00,000=24,00,000 Tablets)	1 Number	3	DILUTED NITROGLYCERIN USP 1.95 %	20.93 mg.
		4	Glyceryl Monosterate (Imwitor 491 powder)	1.255 mg.

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

Case No.	24 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004860AM23
RA File Number	08AX04001421 AM23
Licence No and Date	0811006675/07/12/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202223/22** dated **24/03/2023** against advance authorization No. **0811006399 dated 09/11/2022**, 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.
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 HYDROCHLORIDE 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.	25 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	BIODEAL PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004862AM23
RA File Number	05AX04002637 AM23
Licence No and Date	0511016240/07/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202223/22 dated 24/03/2023** against advance authorization No. **0511015214 dated 11/10/2022**, 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.
NASAL SPRAY(SNAP-ON, S20 WHITE SMOOTH, NASAL ADAPTOR AT PAG136, AM TL 17 ML, 14-0388- 004, WHITE, BOTTLE	99000 Numbers	1	NASAL ADAPTOR FOR MFG OF NASAL SPRAY	Relevant, on Net-to-Net basis with accountability

WITH CHEMICALS AS PER THE DRUG LICENSE)		2	NASAL BOTTLE	Relevant, on Net-to-Net basis with accountability
RA concerned may take further necessary action as per above decision of NC.				

Case No.	26 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004863AM23
RA File Number	52AX04001711 AM23
Licence No and Date	5211003710/07/12/2022

Norms Committee Decision:

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

- 1. Correct chemistry giving chemical reaction and function of import item 1, 3 & 5 in the reaction.**
- 2. Complete calculation based on chemistry of all the raw materials with yield and justification of wastage.**
- 3. Also submit shipping bill and bill of entry of the export products.**

Case No.	27 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	TRANSPEK INDUSTRY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004865AM23
RA File Number	34AX04000797 AM23
Licence No and Date	3411003093/07/12/2022

Norms Committee Decision:

Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.

Case No.	28 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023													
HQ File Number	HQRNORM APPLY 00004866AM23													
RA File Number	08AX04001419 AM23													
Licence No and Date	0811006678/07/12/2022													
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Feb/202223/20 dated 24/02/2023 against advance authorization No.0811006214 dated 10/10/2022, 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:- <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>DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE MONOHYDRATE USED IS 53.000 KGS.])</td> <td>1 Number</td> <td>1</td> <td>DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR.</td> <td>102.908 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.	DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE MONOHYDRATE USED IS 53.000 KGS.])	1 Number	1	DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR.	102.908 mg
Export product	Qty.	Sl. No.	Import items	Qty.										
DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE MONOHYDRATE USED IS 53.000 KGS.])	1 Number	1	DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR.	102.908 mg										

Case No.	29 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004886AM23
RA File Number	34AX04000825 AM23
Licence No and Date	3411003096/08/12/2022
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No.3411002878 dated 11/10/2022, 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.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	30 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004888AM23
RA File Number	09AX04000649 AM23
Licence No and Date	0911004131/08/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Feb/202122/14 dated 21/02/2023** against advance authorization **No.0910069242dated 22/09/2020**, 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.
Tobramycin for Inhalation solution 60 mg / ml (300 mg / 5 ml)	1 Number	1	Tobramycin Sulfate	370.20 mg.
Tobramycin for Inhalation solution 75 mg / ml (300 mg / 4 ml)	1 Number	1	Tobramycin Sulfate	370.20 mg.

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

Case No.	31 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023

HQ File Number	HQRNORM APPLY 00004890AM23																		
RA File Number	05AX04002644 AM23																		
Licence No and Date	0511016259/08/12/2022																		
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202122/14 dated 21/02/2023 against advance authorization No.051044600dated 10/07/2020, 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:- <table border="1" data-bbox="197 646 1434 1013"> <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>ACETAZOLAMIDE TABLETS USP 125 MG</td> <td>1 Number</td> <td>1</td> <td>ACETAZOLAMIDE USP</td> <td>127.50 mg.</td> </tr> <tr> <td>ACETAZOLAMIDE TABLETS USP 250 MG</td> <td>1 Number</td> <td>1</td> <td>ACETAZOLAMIDE USP</td> <td>255.00 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.	ACETAZOLAMIDE TABLETS USP 125 MG	1 Number	1	ACETAZOLAMIDE USP	127.50 mg.	ACETAZOLAMIDE TABLETS USP 250 MG	1 Number	1	ACETAZOLAMIDE USP	255.00 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty.															
ACETAZOLAMIDE TABLETS USP 125 MG	1 Number	1	ACETAZOLAMIDE USP	127.50 mg.															
ACETAZOLAMIDE TABLETS USP 250 MG	1 Number	1	ACETAZOLAMIDE USP	255.00 mg.															

Case No.	32 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004891AM23
RA File Number	05AX04002651 AM23
Licence No and Date	0511016260/08/12/2022
Norms Committee Decision: T The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Get the export item amended to show net content of API in each unit export in line with DML. 2. Copy of DML for each export item. 3. Also submit shipping bill and bill of entry of the export products.	

Case No.	33 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved

Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004896AM23
RA File Number	08AX04001469 AM23
Licence No and Date	0811006711/08/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.1/82-ALC4/2013 dated 04/04/2013 against advance authorization No.0810117768dated 23/01/2013, 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.
MOXONIDINE 0.2MG TABLETS MOXONIDINE HEUMANN 0.2MG (EACH FILM COATED TABLET CONTAINS :MOXONIDINE PH. EUR 0.2MG. NET CONTENT OF MOXONIDINE EP SHOULD NOT BE LESS THAN 3.000 KGS IN EXPORT PRODUCT)	1 tablet	1	MOXONIDINE EP	0.204 mg.
MOXONIDINE 0.3MG TABLETS MOXONIDINE HEUMANN 0.3MG (EACH FILM COATED TABLET CONTAINS:MOXONIDINE PH. EUR 0.3MG. NET CONTENT OF MOXONIDINE EP SHOULD NOT BE LESS THAN 5.250 KGS IN EXPORT PRODUCT)	1 tablet	2	MOXONIDINE EP	0.306 mg.
MOXONIDINE 0.4MGTABLETS MOXONIDINE HEUMANN 0.4MG (EACH FILM COATED TABLET CONTAINS: MOXONIDINE PH. EUR 0.4MG. NET CONTENT OF MOXONIDINE EP SHOULD NOT BE LESS THAN 6.000 KGS IN EXPORTPRODUCT)	1 tablet	3	MOXONIDINE EP	0.408 mg.

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

Case No.	34 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004899AM23
RA File Number	03AX04004574 AM23
Licence No and Date	0311019863/08/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Feb/202223/20 dated 24/02/2023** against advance authorization **No.0311016039dated 03/07/2022**, 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.
TETRA BENZYL THIURAM DISULFIDE(QUREACC TBZTD)(TETRA BENZYL THIURAMDISULFIDE (QUREACC TBZTD))	1 kg.	1	DIBENZYLAMINE	0.74 kg.
		2	CARBON DISULPHIDE	0.285 kg.

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

Case No.	35 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004907AM23
RA File Number	03AX04004528 AM23
Licence No and Date	0311019883/09/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to ratify ad-hoc norms under Para 4.07 of HBP Vol. I considering **NC3 meet March 202223/22 dated 24.03.2023** on prorate basis as per details given below or as applied by the firm, whichever is less: -

Export Product	Qty.	Sl. No.	Import Items	Qty.
Colesevelam HCL for oral suspension 3.75 GM (Per Pack 30 Pouchs)(Colesevelam HCL for oral suspension 3.75 GM (Per Pack 30 Pouchs) (Net. Content of Colesevelam Hydrochloride is 787.50 kgs))	7000 Number Packs	1	Colesevelam Hydrochloride	826.875 kg.

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

Case No.	36 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	KREATIVE ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004909AM23
RA File Number	09AX04000790 AM23
Licence No and Date	0911004140/09/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Jan/202223/18 dated 23/01/2023** against advance authorization **No.0911003550dated 26/08/2022**, 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.
ETODOLAC METHYL ESTER	1 kg.	1	2 ETHYL ANILINE or 2 ETHYL BENZENEAMINE	1.058 kg.
(ETODOLAC METHYL ESTER)		2	2 3 DIHYDROFURANE	0.330 kg.
		3	METHYL 3 OXO PENTONOATE	0.455 kg.

		4	Methanol	1.133 kg.
		5	Toluene	Not shown in the process
		6	Sodium Nitrite	0.40 kg.
		7	Sodium Sulfite	2.20 kg.

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

Case No.	37 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004910AM23
RA File Number	03AX04004432 AM23
Licence No and Date	0311019886/09/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Sep/202223/9 dated 07/10/2022** against advance authorization **No.0311012326dated 07/03/2022**, 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:-

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Rinza sip with Vitamin C (Flavours Orange/ Lemon/ Black Currant/ Other flavours) &(Rinza Sip (Flavours Orange/ Lemon/ Black currant/ Cranberry/ Honey Lemon/ Other flavours). Each sachet of 5gm contains Caffeine Anhydrous Powder 30mg. Net content of Caffeine Anhydrous Powder 923.64 Kgs.)	1 Number Sachet	1	Caffeine Anhydrous Powder	30.30 mg
2	Rinza Tablets. Each tablet Contains Caffeine Anhydrous Powder 30 mg and Paracetamol BP 500 mg.(Net Content of Caffeine Anhydrous Powder - 960 Kgs and	1 Number Tablet	2	Caffeine Anhydrous Powder	30.60 mg
			3	Paracetamol BP	510 mg

	Paracetamol BP- 16000 Kgs)				
3	Rinza Sip for Children (Flavours Raspberry/ other flavours). Each sachet of 3gm contains Paracetamol BP - 280mg.(Net content- 576.92 Kgs.)	1 Number Sachet	4	Paracetamol BP	282.80 mg
RA concerned may take further necessary action as per above decision of NC					

Case No.	38 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004911AM23
RA File Number	05AX04002628 AM23
Licence No and Date	0511016274/09/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to ratify ad-hoc norms under Para 4.07 of HBP Vol. Considering **NC3 meet March 202223/22 dated 24.03.2023** on prorata basis as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Brimonidine Tartrate 0.1% Solution 5ml Santabrim(Brimonidine Tartrate 0.1% Solution 5ml Santabrim)	785299 Vials	1	Brimonidine Tartrate	4.00 kg.

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

Case No.	39 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004917AM23
RA File Number	03AX04004371 AM23
Licence No and	0311019903/12/12/2022

Date				
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.
Medical creams & Ointment (Mesalamine Rectal Suspension, USP Enema 4.0 g/60 ml (Tot Wt: 41777.19 Kgs (Net Cont: Mesalamine 2840.85 Kgs, LDPE Bottle 677981 Nos, Enema Applicator 677981 Nos.))	1 Number	1	Relevant Bulk Drug (Mesalamine USP)	Will decide in due course
		2	Packaging Material	Relevant as per Packing Policy.
		3	Applicator	
RA concerned may take further necessary action as per above decision of NC				

Case No.	40 / NC/3/MEET/Apr/202324/1			
Case Status	Case Approved			
Party Name	SENTISS PHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023			
HQ File Number	HQRNORM APPLY 00004923AM23			
RA File Number	05AX04002676 AM23			
Licence No and Date	0511016292/12/12/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Sep/202223/9 dated 07/10/2022 against advance authorization No.0511006625dated 03/12/2021, 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.

Mydrimax Eye Drops 5 ml (Mydrimax Eye Drops 5 ml) (Each ml Containing 8 mg Tropicamide)	1 Number	1	Tropicamide	40.8 mg / 5 ml vial
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RA concerned may take further necessary action as per above decision of NC.

Case No.	41 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004926AM23
RA File Number	26AX04000074 AM23
Licence No and Date	2611000782/12/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Mar/202223/24 dated 13/04/2023** against advance authorization **No.0911000376dated 18/02/2021**, 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 30 mg (Tamoxifen 30mg (Each Uncoated Tablets Contains: Tamoxifen Citrate Equivalent to Tamoxifen 30 mg))	1 number	1	Tamoxifen citrate	45.60 mg.
		2	Calcium hydrogen phosphate dihydrate	258.40 mg.
		3	Povidone K 25	6.00 mg.
		4	Sodium starch glycolate, type A	30.00 mg.

		5	Magnesium stearate	5.00 mg.
		6	Cellulose microcrystalline	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.	42 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004943AM23
RA File Number	03AX04004593 AM23
Licence No and Date	0311019936/12/12/2022
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products	

Case No.	43 / NC/3/MEET/Apr/202324/1			
Case Status	Case Approved			
Party Name	ADCOCK INGRAM LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023			
HQ File Number	HQRNORM APPLY 00004944AM23			
RA File Number	07AX04001347 AM23			
Licence No and Date	0711005911/12/12/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.6/82-ALC4/2020 dated 13/11/2020 against advance authorization No.0710117061dated 25/09/2020, 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.

NORFLEX 100 mg TABLETS - 1 number (Orphenadrine Citrate 100mg + Lactose 167mg + Aerosil 200 - 8mg + Ethyl Cellulose 20mg) (Orphen-1600.000+ Lactose- 2672.000+Aerosil-128.000+Ethyl-320.000 KGS = Total KGS-4720.000 (No: Tablets: 16000000)BP/EP/USP/PH.EUR/NF/USNF)	1	ORPHENADRINE CITRATE BP/EP/USP/PH.EUR	102.00 mg/tablet
	2	PHARMATOSE 130M MILLED LACTOSE MONOHYDRATE USP-NF/ PH.EUR/JP	R167.00 mg/tablet

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

Case No.	44 / NC/3/MEET/Apr/202324/1			
Case Status	Case Approved			
Party Name	AMOLI ORGANICS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023			
HQ File Number	HQRNORM APPLY 00004960AM23			
RA File Number	03AX04004425 AM23			
Licence No and Date	0311019954/13/12/2022			
Norms Committee Decision:				
.				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No.0311019499dated 24/11/2022 , 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.
Oxcarbazepine USP / BP / EP / IH	1 kg.	1	10-Methoxy Iminostilbene	1.10 kg.

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

Case No.	45 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved

Party Name	ANNORA PHARMA PRIVATE LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023																		
HQ File Number	HQRNORM APPLY 00004967AM23																		
RA File Number	09AX04000796 AM23																		
Licence No and Date	0911004105/13/12/2022																		
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: -																			
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 100 mg/Package (SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 100 mg/Package)</td><td>1 Number</td><td>1</td><td>SAPROPTERIN DIHYDROCHLORIDE</td><td>102.00 mg.</td></tr><tr><td>SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 500 mg/Package (SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 500 mg/Package)</td><td>1 Number</td><td>2</td><td>SAPROPTERIN DIHYDROCHLORIDE</td><td>510.00 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 100 mg/Package (SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 100 mg/Package)	1 Number	1	SAPROPTERIN DIHYDROCHLORIDE	102.00 mg.	SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 500 mg/Package (SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 500 mg/Package)	1 Number	2	SAPROPTERIN DIHYDROCHLORIDE	510.00 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty.															
SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 100 mg/Package (SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 100 mg/Package)	1 Number	1	SAPROPTERIN DIHYDROCHLORIDE	102.00 mg.															
SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 500 mg/Package (SAPROPTERIN DIHYDROCHLORIDE POWDER FOR ORAL SOLUTION 500 mg/Package)	1 Number	2	SAPROPTERIN DIHYDROCHLORIDE	510.00 mg.															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	46 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00004971AM23
RA File Number	31AX04000271 AM23
Licence No and Date	3111001889/13/12/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export	

product/import product in meeting No.NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No.3111001793dated 03/11/2022, 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: -

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty. (in kg.)
(i)	Radicate Spot on 6% for Cats (Pack size 0.75ml x 6 pipettes),(Each ml contains: Selamectin BP 60mg, Net Weight =0.810 Kgs)	3000 Number	1	Selamectin BP / EP / USP	0.825
(ii)	Radicate Spot on 6% for Cats (Pack size 0.75ml x 1 pipettes),(Each ml contains: Selamectin BP 60mg, Net Weight =0.090 Kgs)	2000 Number	2	Selamectin BP / EP / USP	0.092
(iii)	Radicate Spot on 12% for Dog (Small Dog) (Pack size 0.5ml x 1 pipettes),(Each ml contains: Selamectin BP 12%, NetWeight = 0.102 Kgs)	1700 Number	3	Selamectin BP / EP / USP	0.1040
(iv)	Radicate Spot on 12% for Dog (Medium Dog) (Pack size 1 ml x 1 pipettes),(Each ml contains: Selamectin BP 12%,Net Weight = 0.192 Kgs)	1600 Number	4	Selamectin BP / EP / USP	0.1958
(v)	Radicate Spot on 12% for Dog (Large Dog) (Pack size 2 ml x 1 pipettes),(Each ml contains: Selamectin BP 12%, NetWeight = 0.360 Kgs)	1500 Number	5	Selamectin BP / EP / USP	0.368
(vi)	Radicate Spot on 12% for Dog (Extra Large Dog) (Pack size 3 ml x 1 pipettes),(Each ml contains: Selamectin BP 12%,Net Weight = 0.360 Kgs)	1000 Number	6	Selamectin BP / EP / USP	0.368

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

Case No.	47 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	DELTA FINOCHEM PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023

and Date	
HQ File Number	HQRNORM APPLY 00004995AM23
RA File Number	03AX04004505 AM23
Licence No and Date	0311019991/15/12/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Chemistry with molecular weight of both reactant & product giving efficiency of the reaction. 2. COA report of 2& 3 export item and also import item no.1 3. Calculation for the requirement of import item no 2 & 3 duly certified by charter engineer. 4. Also submit shipping bill and bill of entry of the export products.	

Case No.	48 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	B G P HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005000AM23
RA File Number	34AX04000827 AM23
Licence No and Date	3411003121/15/12/2022
Norms Committee Decision: Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	49 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005001AM23
RA File Number	03AX04004455 AM23
Licence No and Date	0311019998/15/12/2022
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No.0311019499dated 24/11/2022, 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.
Oxcarbazepine USP / BP / EP / IH	1 kg.	1	10-Methoxy Iminostilbene	1.10 kg.

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

Case No.	50 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	LAVINIA LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005002AM23
RA File Number	03AX04004301 AM23
Licence No and Date	0311020004/15/12/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Copy of DML showing approved composition of export item. 2. Copy of Master-Batch Formula. 3. Also submit shipping bill and bill of entry of the export products	

Case No.	51 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	VINYL PRODUCTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005004AM23
RA File Number	05AX04002721 AM23
Licence No and Date	0511016406/15/12/2022
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No.0510408806dated 06/12/2018, 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.
PHTHALATE (PVC) PLASTICIZER (DOP)	1 kg.	1	Phthalic Anhydride	0.447 kg.
[PHTHALATE (PVC) PLASTICIZER (DOP)]		2	2 Ethyl Hexanol	0.680 kg.

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

Case No.	52 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	VINYL PRODUCTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005005AM23
RA File Number	05AX04002728 AM23
Licence No and Date	0511016407/15/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization **No.0510408806dated 06/12/2018**, 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.
PHTHALATE (PVC) PLASTICIZER (DOP)	1 kg.	1	Phthalic Anhydride	0.447 kg.
[PHTHALATE (PVC) PLASTICIZER (DOP)]		2	2 Ethyl Hexanol	0.680 kg.

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

Case No.	53 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred

Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005018AM23
RA File Number	09AX04000828 AM23
Licence No and Date	0911004164/15/12/2022
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	54 / NC/3/MEET/Apr/202324/1													
Case Status	Case Approved													
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023													
HQ File Number	HQRNORM APPLY 00005021AM23													
RA File Number	03AX04004519 AM23													
Licence No and Date	0311020036/16/12/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Apr/202223/1 dated 29/04/2022 against advance authorization No.0310796757dated 23/06/2015 , 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:-														
<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">AZITHROMYCIN DIHYDRATE(AZITHROMYCIN DIHYDRATE)</td><td rowspan="2">1 kg.</td><td>1</td><td>AZITHROMYCIN AMINE</td><td>1.04 kg.</td></tr><tr><td>2</td><td>ACETONE</td><td>0.90 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	AZITHROMYCIN DIHYDRATE(AZITHROMYCIN DIHYDRATE)	1 kg.	1	AZITHROMYCIN AMINE	1.04 kg.	2	ACETONE	0.90 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
AZITHROMYCIN DIHYDRATE(AZITHROMYCIN DIHYDRATE)	1 kg.	1	AZITHROMYCIN AMINE	1.04 kg.										
		2	ACETONE	0.90 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	55 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005039AM23
RA File Number	03AX04004536 AM23

Licence No and Date	0311020073/16/12/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jan/202021/4 dated 12/02/2021 against advance authorization No.0310836053dated 01/05/2020 , 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.
GENTAMICIN EAR/EYE DROPS 10 ML((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.030GM NET WT OF BULK DRUG IS 7.49 KGS))	249780 vials	1	Gentamicin Sulphate	9.18 kg.
GENTAMICIN EAR/EYE DROPS 5 ML((EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.015GM NET WT OF BULK DRUG IS 0.69 KGS))	46000 vials	2	Gentamicin Sulphate	0.845 kg.

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

Case No.	56 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005040AM23
RA File Number	03AX04004644 AM23
Licence No and Date	0311020074/16/12/2022
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202223/20 dated 24/02/2023 against advance authorization No.0311015041dated 27/05/2022, 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.
N-HEXYL BROMIDE	1 kg.	1	1-HEXANOL	0.763
		2	HYDROBROMIC ACID 48%	1.260

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

Case No.	57 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005047AM23
RA File Number	05AX04002739 AM23
Licence No and Date	0511016427/16/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Dec/202223/15 dated 29/12/2022** against advance authorization **No.0511013563dated 04/07/2022**, 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.
Deferoxamine Mesylate USP (Sterile Powder)(Deferoxamine Mesylate USP (Sterile Powder))	1 kg.	1	Deferoxamine Mesylate (Non-Sterile)	1.02 kg.

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

Case No.	58 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023

HQ File Number	HQRNORM APPLY 00005069AM23													
RA File Number	09AX04000826 AM23													
Licence No and Date	0911004171/19/12/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to ratify ad-hoc norms under Para 4.07 of HBP Vol. I considering NC3 meet Jan 202223/18 dated 23.01.2023 on prorata basis 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>Daptomycin for Injection 500mg/vial (Consists of Daptomycin 115 Kgs)(Daptomycin for Injection 500mg/vial (Consists of Daptomycin 115 Kgs))</td><td>23000 Numbers</td><td>1</td><td>Daptomycin</td><td>126.5 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Daptomycin for Injection 500mg/vial (Consists of Daptomycin 115 Kgs)(Daptomycin for Injection 500mg/vial (Consists of Daptomycin 115 Kgs))	23000 Numbers	1	Daptomycin	126.5 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
Daptomycin for Injection 500mg/vial (Consists of Daptomycin 115 Kgs)(Daptomycin for Injection 500mg/vial (Consists of Daptomycin 115 Kgs))	23000 Numbers	1	Daptomycin	126.5 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	59 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005075AM23
RA File Number	03AX04004710 AM23
Licence No and Date	0311020115/19/12/2022
Norms Committee Decision:	
Deferred for the comments of TE.Also submit shipping bill and bill of entry of the export products.	

Case No.	60 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	SHREE GANESH REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005087AM23
RA File Number	34AX04000836 AM23
Licence No and Date	3411003129/19/12/2022
Norms Committee Decision:	

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

1. **End use of export product.**
2. **Exact type of residual obtained during distillation and its commercial value.**
3. **Production/Consumption data for last one year duly certified by GST.**
4. **Also submit shipping bill and bill of entry of the export products.**

Case No.	61 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	BIOXERA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005137AM23
RA File Number	03AX04004770 AM23
Licence No and Date	0311020153/20/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No.0311019279dated 17/11/2022, 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.
BENFOTIAMINE(BENFOTIAMINE)	1 kg	1	THIAMINE HYDROCHLORIDE	0.922 kg.

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

Case No.	62 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005138AM23
RA File Number	34AX04000860 AM23
Licence No and Date	3411003138/20/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
Glycopyrrolate injection USP 0.2 mg - 1 ml (Glycopyrrolate injection USP 0.2 mg - 1 ml (net content of active ingredients 75.00 gm))	1 Number	1	Glycopyrrolate USP	0.22 mg.
		2	Serum Stopper (Rubber Stopper)	Relevant as per Packing Policy.
Glycopyrrolate injection USP 0.2 mg - 2 ml (Glycopyrrolate injection USP 0.2 mg - 2 ml (net content of active ingredients 77.00 gm))	1 Number	3	Glycopyrrolate USP	0.44 mg.
		4	Serum Stopper (Rubber Stopper)	Relevant as per Packing Policy.
Glycopyrrolate injection USP 0.2 mg- 5 ml (Glycopyrrolate injection USP 0.2 mg- 5 ml (net content of active ingredients 92.50 gm))	1 Number	5	Glycopyrrolate USP	1.10 mg.
		6	Stopper (Rubber Stopper)	Relevant as per Packing Policy.
Glycopyrrolate injection USP 0.2 mg - 20 ml (Glycopyrrolate injection USP 0.2 mg - 20 ml (net content of active ingredients 20.00 gm))	1 Number	7	Glycopyrrolate USP	4.20 mg.
		8	Serum Stopper (Rubber Stopper)	Relevant as per Packing Policy.

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

Case No.	63 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	RUMIT LIFE CARE
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005139AM23
RA File Number	03AX04004667 AM23
Licence No and	0311020160/20/12/2022

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No.0311018575dated 14/10/2022, 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.
Betamethasone Dipropionate IP/BP/EP/USP (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.	64 / NC/3/MEET/Apr/202324/1			
Case Status	Case Approved			
Party Name	RUMIT LIFE CARE			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023			
HQ File Number	HQRNORM APPLY 00005140AM23			
RA File Number	03AX04004668 AM23			
Licence No and Date	0311020161/20/12/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No.0311018575dated 14/10/2022, 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.
Betamethasone Dipropionate IP/BP/EP/USP (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.	65 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005141AM23
RA File Number	34AX04000846 AM23
Licence No and Date	3411003139/20/12/2022
Norms Committee Decision:	
T	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. Copy of DML for each export items. 2. COA of import item from Foreign Supplier showing potency of import item 3. Wastage applied in each export. 4. Also submit shipping bill and bill of entry of the export products.	

Case No.	66 / NC/3/MEET/Apr/202324/1			
Case Status	Case Approved			
Party Name	INTAS PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023			
HQ File Number	HQRNORM APPLY 00005156AM23			
RA File Number	08AX04001548 AM23			
Licence No and Date	0811006808/21/12/2022			
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:-				

ASPIRIN TABLETS 75 MG (EACH UNCOATED TABLET CONTAINS ACETYL SALICYLIC ACID EP 75 MG)	1 Number	1	ASPIRIN (ACETYL SALICYLIC ACID) EP / BP / IP / USP / PH. EUR.	76.5 mg.
ASPIRIN ENTERIC COATED TABLETS 81 MG "ECOTRIN 81"(EACH ENTERIC COATED TABLET CONTAINS ASPIRIN BP 81 MG [IN WHICH ACTIVE INGREDIENT ASPIRIN (ACETYL SALICYLIC ACID) USED IS 2861.250 KGS.]	1 Number	2	ASPIRIN (ACETYL SALICYLIC ACID) EP / BP / IP / USP / PH. EUR.	82.62 mg.

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

Case No.	67 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005179AM23
RA File Number	34AX04000868 AM23
Licence No and Date	3411003144/21/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202223/22 dated 24/03/2023** against advance authorization No.**3411002878 dated 11/10/2022**, 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.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	68 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005180AM23
RA File Number	34AX04000869 AM23
Licence No and Date	3411003145/21/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Mar/202223/22 dated 24/03/2023** against advance authorization No.**3411002878 dated 11/10/2022**, 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.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	69 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005182AM23
RA File Number	08AX04001545 AM23
Licence No and Date	0811006814/21/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
CINNARIZINE AND DIMENHYDRINATE 20 MG + 40 MG TABLETS (CINZATOR) (EACH UNCOATED TABLETS CONTAINS: CINNARIZINE PH. EUR. 20 MG & DIMENHYDRINATE PH. EUR. 40 MG NET CONTENT OF DIMENHYDRINATE SHOULD NOT BE LESS THAN 30 KGS IN EXPORT PRODUCT)	1 Number	1	DIMENHYDRINATE MICRONIZED PH.EUR	40.80 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	70 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	SHARON BIO-MEDICINE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005222AM23
RA File Number	03AX04004798 AM23
Licence No and Date	0311020213/22/12/2022
Norms Committee Decision:	
Deferred for comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	71 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005239AM23
RA File Number	07AX04001406 AM23
Licence No and Date	0711005991/23/12/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.3/82-ALC4/2018 dated 05/06/2018 against advance authorization No.0710108351 dated 10/06/2015, 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.
CAL - SUP TABLETS (CAL - SUP TABLETS (CALCIUM CARBONATE 1250mg+ GLYCINE 535.7mg) (Glycine - 1000.000 KGS + Calcium - 2333.396 KGS)-Total KGS-3333.396 KGS (No: Tablets: - 1866716) USP/BP/EP)	1 Number	1	GLYCINE USP/BP/EP	535.7 mg/tablet

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

Case No.	72 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005240AM23
RA File Number	03AX04004677 AM23
Licence No and Date	0311020234/23/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.**NC/3/MEET/Mar/202223/22 dated 24/03/2023** against advance authorization **No.0311019482 dated 24/11/2022**, 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:-

S.No.	Export Product	Qty.	Sl.No.	Import Items	Qty.
(i)	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

(ii)	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.
(iii)	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.
(iv)	: Life Brand Sore Throat & Nasal Congestion Relief Extra Strength (Flavours Cherry/Honey & Lemon/Other flavours) (SugarFree Lozenges. Each Lozenge Contains Bezocaine 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.
(v)	Personnelle Oral Anesthetic Sore Throat Lozenges Extra Strenght Sugar Free (Flavours Cherry/Honey Lemon/Other flavours) (Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2571 Mg. Net Content Benzocaine 9.934 Kgs and Isomalt ST-M - 1702.742Kgs.)	1 Number	6	Benzocaine	15.30 mg.
			7	Isomalt ST-M	2571.00 mg
(vi)	Option+Oral Lozenges Sore Throat & Nasal Congestion Relief Extra Strenght (Flavours Cherry/Honey Lemon /Other flavours). (Each Lozenge Contains Bezocaine 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.
(vii)	Biomedic Oral Anesthetic Lozenges Sore Throat & Nasal Congestion Relief Extra Strength Cherry ST & NCRELEX (Lozenges(FlavoursCherry/HoneyLemon/Otherflavours)Each LozengeContainsBezocaine15mg&IsomaltST-M2571 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
(viii)	Atoma Sore Throat & Nasal Congestion Relief Extra Strength Lozenges Cherry/Honey & Lemon Flavour.(Each Lozenge Contains Bezocaine 15 mg & Isomalt ST-M 2700 Mg. Net	1 Number	12	Benzocaine	15.30 mg.
			13	Isomalt	2700.00

	Content Benzocaine 6.623 Kgs and Isomalt ST-M - 1135.148 Kgs.)			ST-M	mg.
RA concerned may take further necessary action as per above decision of NC.					

Case No.	73 / NC/3/MEET/Apr/202324/1													
Case Status	Case Approved													
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023													
HQ File Number	HQRNORM APPLY 00005244AM23													
RA File Number	08AX04001456 AM23													
Licence No and Date	0811006827/23/12/2022													
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:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>Isoproterenol Hydrochloride Injection USP, 0.2mg/ml (5ml)</td><td>1 Number</td><td>1</td><td>Isoproterenol HydrochlorideInjection,USP1mg/5ml(0.2mg/ml)</td><td>1.10 mg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Isoproterenol Hydrochloride Injection USP, 0.2mg/ml (5ml)	1 Number	1	Isoproterenol HydrochlorideInjection,USP1mg/5ml(0.2mg/ml)	1.10 mg
Export Product	Qty.	Sl. No.	Import Items	Qty.										
Isoproterenol Hydrochloride Injection USP, 0.2mg/ml (5ml)	1 Number	1	Isoproterenol HydrochlorideInjection,USP1mg/5ml(0.2mg/ml)	1.10 mg										
RA concerned may take further necessary action as per above decision of NC														

Case No.	74 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005247AM23
RA File Number	08AX04001457 AM23
Licence No and Date	0811006828/23/12/2022
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for	

following information/documents from the firm:-

1. **Both export and import items are same. Appears to be an error. Firm may be advised to get the license amended.**
2. **Also submit shipping bill and bill of entry of the export products.**

Case No.	75 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005250AM23
RA File Number	05AX04002812 AM23
Licence No and Date	0511016521/23/12/2022

Norms Committee Decision:

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

1. **Approved composition of export item.**
2. **Copy of Master Batch Formula.**
3. **COA of export item.**
4. **COA of Import item from Foreign Supplier**
5. **Wastage claimed.**
6. **Also submit shipping bill and bill of entry of the export products.**

Case No.	76 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005251AM23
RA File Number	34AX04000877 AM23
Licence No and Date	3411003175/23/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202223/22 dated 24/03/2023** against advance authorization No. **3411002878 dated 11/10/2022**, 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.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	77 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005256AM23
RA File Number	34AX04000871 AM23
Licence No and Date	3411003177/23/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Feb/202223/20 dated 24/02/2023** against advance authorization **No.3411001750 dated 04/02/2022**, 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.
Undecavertol (Kakdinol) ((4-Methyl-3-decen- 5-ol))	1 kg.	1	Propionaldehyde	0.842 kg.
		2	1-Pentanol / N Amyl Alcohol	0.639 kg.
		3	Magnesium Turning	0.142 kg.

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

Case No.	78 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023

HQ File Number	HQRNORM APPLY 00005272AM23
RA File Number	05AX04002766 AM23
Licence No and Date	0511016533/26/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202223/22 dated 24/03/2023** against advance authorization **No.0511015457 dated 21/10/2022**, 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.(in kg.)
CEFTIBUTEN JP(POWDER)	1 kg.	1	Pencillin G Potassium First Crystal	8.515
		2	METHYLENE CHLORIDE /Dichloromethane	76.165
		3	Triethylamine	3.214
		4	Methanol	41.137
		5	Ethyl-4-chloroacetoacetate	1.82
		6	Methyl-3-methoxy acrylate	1.62
		7	Prenol	3.114
		8	N,N-Dimethyl Formamide	12.16
		9	Acetonitrile	7.50
		10	Activated carbon	0.200
		11	Acetone	1.20
		12	Toluene	23.00

		13	Acetic acid	5.50
RA concerned may take further necessary action as per above decision of NC.				

Case No.	79 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005274AM23
RA File Number	03AX04004717 AM23
Licence No and Date	0311020258/26/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Oct/202223/11 dated 31/10/2022** against advance authorization **No.0311009599 dated 17/12/2021**, 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.
CEFEPIME FOR INJECTION (CEFEPIME FOR INJECTION)	1 kg.	1	CEFEPIME HCL NON STERILE	0.655 kg.
		2	LARGININE	0.370 kg.
		3	PACKING MATERIALS	Relevant as per packing policy

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

Case No.	80 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	AURA PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023

HQ File Number	HQRNORM APPLY 00005276AM23
RA File Number	03AX04004700 AM23
Licence No and Date	0311020263/26/12/2022
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	81 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005281AM23
RA File Number	07AX04001346 AM23
Licence No and Date	0711005988/26/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. 7/82-ALC4/2019 dated 06/09/2019** against advance authorization **No.0710111042 dated 31/01/2017**, 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.
Glycopyrrolate Injection USP 0.2mg/mL- 1ml 2ml 5ml Vial Each ml contains 0.2mg of Glycopyrrolate as Bulk Drug(TotalExport Qty 991094 Vials of which 380000 nos are 1ml vial and 360568 nos are 2ml vial and 250526 Vials are 5ml vial for which total export Qty is 991094 nos required for considering 10% wastage as per SION(A205))	900994.0 Numbers	1	(V-35 4432/50/GREY Westar? RS SIL 1)13mm Chlorobutyl R/S V-35 4432/50 Grey - RFS	Relevant as per Packing Policy.

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

Case No.	82 / NC/3/MEET/Apr/202324/1
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Case Status	Case Deferred
Party Name	KAVALIFE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005283AM23
RA File Number	07AX04001408 AM23
Licence No and Date	0711006001/26/12/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Difference between Import and Export item. 2. Complete COA of import from supplier. 3. COA of complete export giving% of another component. 4. Justification of wastage claimed. 5. Also submit shipping bill and bill of entry of the export products.	

Case No.	83 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005300AM23
RA File Number	09AX04000869 AM23
Licence No and Date	0911004207/26/12/2022
Norms Committee Decision: Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	84 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005306AM23
RA File Number	07AX04001424 AM23
Licence No and Date	0711006015/26/12/2022
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No.0711003587 dated 03/04/2022, 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.
Sterile Water for Injection 10mL Vial(Sterile Water for injection, filled in 10mL Vial and capped with 13mmGreySerum Chlorobutyl Rubber Stopper)	900000 Numbers	1	13mm GraySerum Chlorobutyl R/S-RFS-C14226422GS6TP3	Relevant as per Packing Policy

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

Case No.	85 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	VACHICHEM INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005310AM23
RA File Number	07AX04001398 AM23
Licence No and Date	0711006018/26/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Sep/202223/8 dated 23/09/2022** against advance authorization **No.0711002024 dated 30/09/2021**, 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.
6-(2-PROPENY)-ERGOLINE-8-CARBOXYLIC ACID CAS NO 81409-74-7(6-(2-PROPENY)-ERGOLINE-8- CARBOXYLIC ACID CAS NO 81409-74-7)	1 kg.	1	LYSERGOL (9,10 DIDEHYDRO 6-METHYLERGOLINE -8B-METHANOL CAS NO 602-85-7)	2.98 kg.

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

Case No.	86 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005311AM23
RA File Number	03AX04004688 AM23
Licence No and Date	0311020288/27/12/2022
Norms Committee Decision:	
Deferred for the comments of TE. Also call shipping bill and bill of entry.	

Case No.	87 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005317AM23
RA File Number	07AX04001362 AM23
Licence No and Date	0711006024/27/12/2022
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	88 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	LYRUS LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005325AM23
RA File Number	07AX04001423 AM23
Licence No and Date	0711006029/27/12/2022
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Copy of DML for each export item. 2. Detailed calculation/Justification for the import quantity in line with DML. 3. Also submit shipping bill and bill of entry of the export products.	

Case No.	89 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	CANPEX CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005335AM23
RA File Number	31AX04000284 AM23
Licence No and Date	3111001917/27/12/2022
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	90 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	INDIA GLYCOLS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005340AM23
RA File Number	05AX04002859 AM23
Licence No and Date	0511016572/27/12/2022
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Activity % of Silver Catalyst. 2. Function of Alumina Catalyst in the reaction with its activity %. 3. Also submit shipping bill and bill of entry of the export products	

Case No.	91 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005380AM23
RA File Number	34AX04000907 AM23
Licence No and Date	3411003203/28/12/2022
Norms Committee Decision:	
. The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance	

authorization No. **3411002878 dated 11/10/2022**, 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.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	92 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005381AM23
RA File Number	07AX04001433 AM23
Licence No and Date	0711006048/28/12/2022

Norms Committee Decision:

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

- 1. Copy of Master Batch Formula showing net content of inputs in the export item.**
- 2. Also submit shipping bill and bill of entry of the export products.**

Case No.	93 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005387AM23
RA File Number	05AX04002796 AM23
Licence No and Date	0511016607/28/12/2022

Norms Committee Decision:

Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.

Case No.	94 / NC/3/MEET/Apr/202324/1
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Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005395AM23
RA File Number	07AX04001425 AM23
Licence No and Date	0711006007/28/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jun/202122/2 dated 02/07/2021** against advance authorization No. **0711000869 dated 09/04/2021**, 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.
Bumetanide Injection 0.25mg/mL, 4mL vial (Bumetanide Injection 0.25mg/mL, 4mL vial -0.25 mg of bulk drug filled in 4 mL vial and sealed with 13mm stopper)	259600 Numbers	1	V-35 4416/50 GRY SIL 3 Westar SELECT RS/ P02(13mm stopper) RFS-V-35 4416/50 GRY SIL Westar RS/SP02-R/S	Relevant as per packing policy
Bumetanide Injection 0.25mg/mL, 10mL vial (Bumetanide Injection 0.25mg/mL, 10mL vial -0.25 mg of bulk drug filled in 10 mL vial and sealed with 13mm stopper)	189200 Numbers	2	V-35 4416/50 GRY SIL 3 Westar SELECT RS/ P02(13mm stopper) RFS-V-35 4416/50 GRY SIL Westar RS/SP02-R/S	Relevant as per packing policy
Famotidine Injection 10mg/mL, 2mL vial (Famotidine Injection 10mg/mL, 2mL vial -10mg of bulk drug filled in 2mL vial and sealed with 13mm stopper)	748000 Numbers	3	V-35 4416/50 GRY SIL 3 Westar SELECT RS/ P02(13mm stopper) RFS-V-35 4416/50 GRY SIL Westar RS/SP02-R/S	Relevant as per packing policy

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

Case No.	95 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005401AM23
RA File Number	34AX04000903 AM23
Licence No and Date	3411003211/29/12/2022
Norms Committee Decision:	
Deferred for the comments of TE.Also submit shipping bill and bill of entry of the export products.	

Case No.	96 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	CENTRIENT PHARMACEUTICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005408AM23
RA File Number	30AX04000407 AM23
Licence No and Date	3011002957/29/12/2022
Norms Committee Decision:	
Deferred for the comments of TE.Also submit shipping bill and bill of entry of the export products.	

Case No.	97 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	VINYL PRODUCTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005409AM23
RA File Number	05AX04002878 AM23
Licence No and Date	0511016621/29/12/2022
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms 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.
- vi. Also submit shipping bill and bill of entry of the export products.

Case No.	98 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	COHANCE LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005417AM23
RA File Number	09AX04000884 AM23
Licence No and Date	0911004233/29/12/2022
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	99 / NC/3/MEET/Apr/202324/1										
Case Status	Case Approved										
Party Name	ALEMBIC PHARMACEUTICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023										
HQ File Number	HQRNORM APPLY 00005422AM23										
RA File Number	34AX04000894 AM23										
Licence No and Date	3411003198/29/12/2022										
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:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty.</th></tr><tr><td>Mesalamine Extended Release Capsules 0.375 gm (Mesalamine Extended Release Capsules 0.375 gm (Net content of active Ingredient - 1237.50 kgs.))</td><td>1 Number</td><td>1</td><td>MESALAMINE USP DENSE GRADE 9151</td><td>382.5 mg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	Mesalamine Extended Release Capsules 0.375 gm (Mesalamine Extended Release Capsules 0.375 gm (Net content of active Ingredient - 1237.50 kgs.))	1 Number	1	MESALAMINE USP DENSE GRADE 9151	382.5 mg
Export Product	Qty.	Sl. No.	Import Items	Qty.							
Mesalamine Extended Release Capsules 0.375 gm (Mesalamine Extended Release Capsules 0.375 gm (Net content of active Ingredient - 1237.50 kgs.))	1 Number	1	MESALAMINE USP DENSE GRADE 9151	382.5 mg							

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

Case No.	100 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005430AM23
RA File Number	03AX04004553 AM23
Licence No and Date	0311020346/30/12/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Complete chemical reactions, Molecular weight and % yield on molar basis. 2. Also submit shipping bill and bill of entry of the export products.	

Case No.	101 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005431AM23
RA File Number	03AX04004543 AM23
Licence No and Date	0311020347/30/12/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Complete chemical reactions, Molecular weight and % yield on molar basis. 2. Also submit shipping bill and bill of entry of the export products.	

Case No.	102 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	COHANCE LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005432AM23
RA File Number	09AX04000883 AM23
Licence No and Date	0911004235/30/12/2022

Norms Committee Decision:

Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.

Case No.	103 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005439AM23
RA File Number	04AX04000856 AM23
Licence No and Date	0411004696/30/12/2022

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.
IBUPROFEN	1 Kg.	1	2-(4- (Isobutyl Phenyl)Propanaldehyde	1.085 kg.
		2	Sodium Dichromate	0.630 kg.

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

Case No.	104 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	CENTRIENT PHARMACEUTICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005440AM23
RA File Number	30AX04000435 AM23
Licence No and Date	3011002966/30/12/2022

Norms Committee Decision:

Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.

Case No.	105 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred

Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005442AM23
RA File Number	05AX04002802 AM23
Licence No and Date	0511016635/30/12/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Approved composition of export item. 2. Copy of Master-Batch Formula. 3. Justification for 20% wastage on Import item no. 1. and Nil on wastage on Import item No.2. 4. Material balance for entire process. 5. Also submit shipping bill and bill of entry of the export products	

Case No.	106 / NC/3/MEET/Apr/202324/1										
Case Status	Case Approved										
Party Name	SIDDHARTH CARBOCHEM PRODUCTS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023										
HQ File Number	HQRNORM APPLY 00005445AM23										
RA File Number	03AX04004857 AM23										
Licence No and Date	0311020368/30/12/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Sep/202223/8 dated 23/09/2022 against advance authorization No. 0311008684 dated 19/11/2021 , 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:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>METHYL SALICYLATE (MIN 99 PERCENT) (PHENOL FREE)</td><td>1 kg.</td><td>1</td><td>SALICYLIC ACID</td><td>0.955 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	METHYL SALICYLATE (MIN 99 PERCENT) (PHENOL FREE)	1 kg.	1	SALICYLIC ACID	0.955 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.							
METHYL SALICYLATE (MIN 99 PERCENT) (PHENOL FREE)	1 kg.	1	SALICYLIC ACID	0.955 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	107 / NC/3/MEET/Apr/202324/1										
Case Status	Case Approved										
Party Name	DEEPAK PHENOLICS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023										
HQ File Number	HQRNORM APPLY 00005447AM23										
RA File Number	34AX04000911 AM23										
Licence No and Date	3411003217/30/12/2022										
Norms Committee Decision: T The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No. 3411002878 dated 11/10/2022, 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:- <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>Phenol</td><td>1 MT</td><td>1</td><td>Cumene</td><td>0.84466 MT</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.	Phenol	1 MT	1	Cumene	0.84466 MT
Export Product	Qty.	Sl. No.	Import Items	Qty.							
Phenol	1 MT	1	Cumene	0.84466 MT							

Case No.	108 / NC/3/MEET/Apr/202324/1					
Case Status	Case Approved					
Party Name	SAURAV CHEMICALS LIMITED					
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023					
HQ File Number	HQRNORM APPLY 00005449AM23					
RA File Number	30AX04000443 AM23					
Licence No and Date	3011002971/30/12/2022					
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:- <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.		

DEXKETOPROFEN TROMETAMOL	1 Kg.	1	KETOPROFEN	1.00 kg.
		2	N OCTYL D GLUCAMINE	0.36 kg.
		3	TRIS AMINO BUFFER TROMETHAMINE	0.36 kg.

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

Case No.	109 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	ZENITH DYEINTERMEDIATES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005458AM23
RA File Number	03AX04004689 AM23
Licence No and Date	0311020392/02/01/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. Chemistry of reaction giving complete calculation for requirements of raw materials based on molecular height. 2. Yield of the reaction with justification. 3. To fill 4E annexure indicating imported & indigenous items. 4. Production/consumption for last three years duly certify by CA. 5. Also submit shipping bill and bill of entry of the export products.	

Case No.	110 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	SPAK ORGOCHEM (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005464AM23
RA File Number	03AX04004881 AM23
Licence No and Date	0311020403/02/01/2023
Norms Committee Decision:	

The Committee considered the case as per agenda and 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.
Sorbitan Mono Laurate	1 Kg.	1	Palm Kernel Fatty Acid/Coconut Fatty Acid (95% Active Content)	0.66 kg.
		2	SORBITOL 70% SOLUTION	0.71 kg.

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

Case No.	111 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005480AM23
RA File Number	03AX04004595 AM23
Licence No and Date	0311020433/03/01/2023
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	112 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	MACLEODS PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005484AM23
RA File Number	03AX04004899 AM23
Licence No and Date	0311020446/03/01/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jan/202223/18 dated 23/01/2023 against advance authorization No. 0311003736 dated 12/05/2021, 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.
Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 3080.240 kgs Dolutegravir Sodium + 18481.440 kgs Tenofovir Disoproxil Fumarate + 18481.440 kgs Lamivudine))	1 Number	1	(R)-3-AMINO-1-BUTANOL	19.635 mg
		2	1-(2,2-dimethoxyethyl)-5-methoxy-6(methoxycarbonyl) 4-oxo-1,4-dihydropyridine-3-carboxylic acid	Indigenously procured
		3	Lithium bromide anhydrous	Indigenously procured
		4	(R)-9-(2-phosphonomethoxy propyl)-adenine	205.02 mg
		5	LAMIVUDINE	Indigenously procured

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

Case No.	113 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005486AM23
RA File Number	05AX04002919 AM23
Licence No and Date	0511016690/03/01/2023

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.
Tobramycin Inhalation Solution, USP, 300mg/ 4ml (Having net content of 23.10 kg of Bulk drug)	1 Number	1	TOBRAMYCIN USP	306 mg.

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

Case No.	114 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005487AM23
RA File Number	30AX04000416 AM23
Licence No and Date	3011002973/03/01/2023
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	115 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005490AM23
RA File Number	03AX04004959 AM23
Licence No and Date	0311020450/03/01/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jan/202223/18 dated 23/01/2023** against advance authorization No. **0311013612 dated 05/04/2022**, 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. (in mg)
Atorvastatin Calcium Tablets USP 10mg((Net wt. of Import Sr. No. 1 is 495.945kgs, Sr. No. 2 is 2746.71kg, Sr. No. 3 is 779.985kg, Sr. No. 4 is 505000 Nos.))	1 Number 1 Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415
		2	Microcrystalline	64.578

			Cellulose (MCC) NF (Avicel PH 102)	
		3	Calcium Acetate	18.049
		4	Silica Gel Dessicants - Relevant as Packaged Activated per Carbon (Strippax packing Sorbent) policy	
Atorvastatin Calcium Tablets USP 20mg((Net wt. of Import Sr. No. 1 is 59.513kgs, Sr. No. 2 is 330.772kg, Sr. No. 3 is 93.879kg, Sr. No. 4 is 30300 Nos.))	1 Number	5	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830
		6	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427
		7	Calcium Acetate	36.090
		8	Silica Gel Dessicants - Relevant as Packaged Activated per Carbon (Strippax packing Sorbent) policy	
Atorvastatin Calcium Tablets USP 40mg((Net wt. of Import Sr. No. 1 is 3570.804kgs, Sr. No. 2 is 19777.77kg, Sr. No. 3 is 5616.216kg, Sr. No. 4 is 909000 Nos.))	1 Number	9	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595
		10	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08
		11	Calcium Acetate	71.963
		12	Silica Gel Dessicants - Relevant as Packaged Activated per Carbon (Strippax packing Sorbent) policy	

Atorvastatin Calcium Tablets USP 80mg((Net wt. of Import Sr. No. 1 is 2459.8871kgs, Sr. No. 2 is 13690.223kg, Sr.No. 3 is 3884.712kg, Sr. No. 4 is 313100 Nos.))	1	Number	13	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20
			14	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206
			15	Calcium Acetate	144.929
			16	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant as per packing policy
Note: The above norms are valid only for subject to fulfillment of following conditions: - 1. Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application) of Apotex Corp, US. Agent for Apotex Inc., Canada. 2. Export to USA only. 3. Firm holding Certificate of Manufacturing Exclusivity.					

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

Case No.	116 / NC/3/MEET/Apr/202324/1			
Case Status	Case Approved			
Party Name	PIRAMAL PHARMA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023			
HQ File Number	HQRNORM APPLY 00005496AM23			
RA File Number	03AX04004960 AM23			
Licence No and Date	0311020457/04/01/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Dec/202223/17 dated 13/01/2023 against advance authorization No. 0311017097 dated 11/08/2022 , 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.

Bempedoic Acid and Ezetimibe Fixed Dose Combination Tablets (Each Tablet content Bempedoic Acid 180mg and Ezetimibe 10mg((Net content of Bempedoic Acid 2700 kgs and Ezetimibe 150 kgs in total Export Qty) (AA for Free of cost material as per Para 4.11 of HBP &Para 4.19 of FTP &RBI Master Circular C-26 - Disallowing remittances for material being supplied free of cost))	1 Number	1	Bempedoic Acid	189.90 mg
		2	Ezetimibe	10.55 mg

Note: The above norms are valid only for subject to fulfillment of following conditions:

- 1. Export Product being Patented Medicine, be filed with USFDA as an NDA (New Drug Application.**
- 2. Export to USA and Europe only.**
- 3. Firm holding Certificate of Manufacturing Exclusivity.**

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

Case No.	117 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	ZEOLITES AND ALLIED PRODUCTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005510AM23
RA File Number	03AX04004898 AM23
Licence No and Date	0311020475/04/01/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to justify from the firm on following issue: - 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. Also submit shipping bill and bill of entry of the export products.	

Case No.	118 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	RAKSHIT DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005513AM23
RA File Number	09AX04000866 AM23
Licence No and Date	0911004255/04/01/2023
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	119 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005526AM23
RA File Number	09AX04000891 AM23
Licence No and Date	0911004257/04/01/2023
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	120 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	VHB MEDI SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005528AM23
RA File Number	03AX04004952 AM23
Licence No and Date	0311020485/04/01/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jan/202021/4 dated 12/02/2021 against advance authorization No. 0310834259 dated 16/01/2020 , 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:-	

COLISIN-RD 1MIU Injection (COLISTIMETHATE SODIUM BP for injection 1 MIU) (Net content of Import item = 5.101 kgs)(COLISIN-RD 1MIU Injection (COLISTIMETHATE SODIUM BP for injection 1 MIU) (Net content of Import item = 5.101 kgs))	66250 Numbers	1	COLISTIMETHAT SODIUM STERILE EP	E5.20 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	121 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005545AM23
RA File Number	07AX04001477 AM23
Licence No and Date	0711006102/05/01/2023
Norms Committee Decision:	
Deferred for comments of TE Also submit shipping bill and bill of entry of the export products.	

Case No.	122 / NC/3/MEET/Apr/202324/1			
Case Status	Case Approved			
Party Name	BIODEAL PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023			
HQ File Number	HQRNORM APPLY 00005556AM23			
RA File Number	05AX04002933 AM23			
Licence No and Date	0511016741/05/01/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jan/202223/18 dated 23/01/2023 against advance authorization No. 0511014609 dated 02/09/2022 , 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.

NASAL SPRAY(U SAVE DE 6 ML CLEAR GLASS TYPE 1, NECK FINISH FEA 20, GLASS BOTTLE WITH CHEMICALS AS PER THE DRUG LICENSE)	99000 Numbers	1	NASAL BOTTLE	Relevant, on Net to Net basis with accountability
RA concerned may take further necessary action as per above decision of NC.				

Case No.	123 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	BIODEAL PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005557AM23
RA File Number	05AX04002931 AM23
Licence No and Date	0511016742/05/01/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jan/202223/18 dated 23/01/2023** against advance authorization No. **0511014609 dated 02/09/2022**, 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.
NASAL SPRAY (U SAVE DE 6 ML CLEAR GLASS TYPE 1, NECK FINISH FEA 20, GLASS BOTTLE WITH CHEMICALS AS PER THE DRUG LICENSE)	99000 Numbers	1	NASAL BOTTLE	Relevant, on Net-to-Net basis with accountability

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

Case No.	124 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	BIODEAL PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005558AM23
RA File Number	05AX04002932 AM23
Licence No and Date	0511016743/05/01/2023
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	125 / NC/3/MEET/Apr/202324/1			
Case Status	Case Approved			
Party Name	INTAS PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023			
HQ File Number	HQRNORM APPLY 00005567AM23			
RA File Number	08AX04001580 AM23			
Licence No and Date	0811006936/05/01/2023			
Norms Committee Decision:				
T				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No. 0811006399 dated 09/11/2022 , 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.
NALTREXONE HYDROCHLORIDE TABLETS USP 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE USP 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 76.050 KGS.])	1 Number	1	NALTREXONE HYDROCHLORID 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.	126 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005568AM23
RA File Number	34AX04000926 AM23
Licence No and Date	3411003231/05/01/2023
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	127 / NC/3/MEET/Apr/202324/1															
Case Status	Case Approved															
Party Name	CIPLA LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023															
HQ File Number	HQRNORM APPLY 00005573AM23															
RA File Number	03AX04004890 AM23															
Licence No and Date	0311020522/06/01/2023															
Norms Committee Decision:																
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Dec/202223/15 dated 29/12/2022 against advance authorization No. 0311015826 dated 24/06/2022 , 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: -																
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty.</th></tr><tr><td>Telmisartan and Amlodipine Tablets 40/10mg / Each uncoated tablets contains: Telmisartan 40 mg(Telmisartan 40 mgequivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is2,020.800 Kgs. Net wt of Amlodipine Besilate is 300.000 Kgs.)</td><td>1 Number</td><td>1</td><td>Amlodipine Besilate</td><td>10.20 mg</td></tr><tr><td>Telmisartan and Amlodipine Tablets 80/10mg / Each uncoated tablets contains: Telmisartan 80 mg (Telmisartan 80</td><td>1 Number</td><td>2</td><td>Amlodipine Besilate</td><td>10.20 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	Telmisartan and Amlodipine Tablets 40/10mg / Each uncoated tablets contains: Telmisartan 40 mg(Telmisartan 40 mgequivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is2,020.800 Kgs. Net wt of Amlodipine Besilate is 300.000 Kgs.)	1 Number	1	Amlodipine Besilate	10.20 mg	Telmisartan and Amlodipine Tablets 80/10mg / Each uncoated tablets contains: Telmisartan 80 mg (Telmisartan 80	1 Number	2	Amlodipine Besilate	10.20 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty.												
Telmisartan and Amlodipine Tablets 40/10mg / Each uncoated tablets contains: Telmisartan 40 mg(Telmisartan 40 mgequivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is2,020.800 Kgs. Net wt of Amlodipine Besilate is 300.000 Kgs.)	1 Number	1	Amlodipine Besilate	10.20 mg												
Telmisartan and Amlodipine Tablets 80/10mg / Each uncoated tablets contains: Telmisartan 80 mg (Telmisartan 80	1 Number	2	Amlodipine Besilate	10.20 mg.												

mgequivalent to Telmisartan granules 134.72mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is 10,777.600 Kgs. Net wt of Amlodipine Besilate is 800.000 Kgs.)				
Telmisartan and Amlodipine Tablets 40/5mg / Each uncoated tablets contains: Telmisartan 40 mg (Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 5mg Net wt of Telmisartan Granules is 6,286.933 Kgs. Net wt of Amlodipine Besilate is 466.667 Kgs.)	1 Number	3	Amlodipine Besilate	5.10 mg.
Telmisartan and Amlodipine Tablets 80/5mg / Each uncoated tablets contains: Telmisartan 80 mg (Telmisartan 80 mgequivalent to Telmisartan granules 134.72mg Amlodipine Besilate equivalent to Amlodipine USP 5mg Net wt of Telmisartan Granules is 10,777.600 Kgs. Net wt of Amlodipine Besilate is 400.000 Kgs.)	1 Number	4	Amlodipine Besilate	5.10 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	128 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005588AM23
RA File Number	05AX04002947 AM23
Licence No and Date	0511016763/06/01/2023
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	129 / NC/3/MEET/Apr/202324/1
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Case Status	Case Deferred
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005594AM23
RA File Number	07AX04001479 AM23
Licence No and Date	0711006109/06/01/2023
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	130 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005595AM23
RA File Number	07AX04001473 AM23
Licence No and Date	0711006137/06/01/2023
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	131 / NC/3/MEET/Apr/202324/1			
Case Status	Case Approved			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023			
HQ File Number	HQRNORM APPLY 00005596AM23			
RA File Number	07AX04001471 AM23			
Licence No and Date	0711006138/06/01/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jan/202223/18 dated 23/01/2023 against advance authorization No. 0711005273 dated 19/09/2022 , 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.

TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML (TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10MG (226.44KG))	1 Number	1	TRANEXAMIC ACID	1100 mg/ 10 ml Vial
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RA concerned may take further necessary action as per above decision of NC.

Case No.	132 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005598AM23
RA File Number	07AX04001475 AM23
Licence No and Date	0711006139/06/01/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Dec/202223/15** dated **29/12/2022** against advance authorization No. **0711004345** dated **17/06/2022**, 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.
Sodium Chloride Injection USP 90mg per 10mL Vial.(Sodium Chloride Injection USP 90mg per 10mL Vial - filled with 90mg of Sodium Chloride as bulk drug filled in 10mL Vial and capped with 13mm Grey Serum Chlorobutyl Rubber Stopper)	1 Number	1	10ml Unprinted Clear Glass Vial Zenith	Relevant as per packing policy

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

Case No.	133 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved

Party Name	MACLEODS PHARMACEUTICALS LTD																			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023																			
HQ File Number	HQRNORM APPLY 00005605AM23																			
RA File Number	03AX04005022 AM23																			
Licence No and Date	0311020561/09/01/2023																			
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jan/202223/18 dated 23/01/2023 against advance authorization No. 0311003736 dated 12/05/2021, 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:- <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">Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 3690.000 kgs Dolutegravir Sodium + 22140.000 kgs Tenofovir Disoproxil Fumarate + 22140.000 kgs Lamivudine))</td><td rowspan="4">1 Number</td><td>1</td><td>(R)-3-AMINO-1-BUTANOL</td><td>19.635 mg.</td></tr> <tr> <td>2</td><td>1-(2,2-dimethoxyethyl)-5-methoxy-6(methoxycarbonyl)-4-oxo-1,4-dihydropyridine-3-carboxylic acid</td><td>Indigenously procured</td></tr> <tr> <td>3</td><td>(R)-9-(2-phosphonomethoxy propyl)-adenine</td><td>205.02 mg</td></tr> <tr> <td>4</td><td>LAMIVUDINE</td><td>Indigenously procured</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.	Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 3690.000 kgs Dolutegravir Sodium + 22140.000 kgs Tenofovir Disoproxil Fumarate + 22140.000 kgs Lamivudine))	1 Number	1	(R)-3-AMINO-1-BUTANOL	19.635 mg.	2	1-(2,2-dimethoxyethyl)-5-methoxy-6(methoxycarbonyl)-4-oxo-1,4-dihydropyridine-3-carboxylic acid	Indigenously procured	3	(R)-9-(2-phosphonomethoxy propyl)-adenine	205.02 mg	4	LAMIVUDINE	Indigenously procured
Export Product	Qty.	Sl. No.	Import Items	Qty.																
Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 3690.000 kgs Dolutegravir Sodium + 22140.000 kgs Tenofovir Disoproxil Fumarate + 22140.000 kgs Lamivudine))	1 Number	1	(R)-3-AMINO-1-BUTANOL	19.635 mg.																
		2	1-(2,2-dimethoxyethyl)-5-methoxy-6(methoxycarbonyl)-4-oxo-1,4-dihydropyridine-3-carboxylic acid	Indigenously procured																
		3	(R)-9-(2-phosphonomethoxy propyl)-adenine	205.02 mg																
		4	LAMIVUDINE	Indigenously procured																

Case No.	134 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	RAKSHIT PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005612AM23
RA File Number	09AX04000843 AM23
Licence No and Date	0911004282/09/01/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202223/24 dated 13/04/2023 against advance authorization No. 0911002001 dated 06/12/2021, 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.
Mycophenolate Sodium(Solid)	1 kg.	1	Mycophenolic Acid	0.90 kg.
		2	Toluene	0.66 kg.
		3	Methanol	0.70 kg.

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

Case No.	135 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	BIODEAL PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005629AM23
RA File Number	05AX04002930 AM23
Licence No and Date	0511016789/10/01/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202223/22** dated **24/03/2023** against advance authorization No. **0511015214 dated 11/10/2022**, 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.
NASAL SPRAY(SNAP-ON, S20 WHITE SMOOTH, NASAL ADAPTOR WITH CHEMICALS AS PER THE DRUG LICENSE)	99000 Numbers	1	SNAP-ON, S20 WHITE SMOOTH, NASAL ADAPTOR 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.	136 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	APOTHECARY PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005666AM23
RA File Number	31AX04000290 AM23
Licence No and Date	3111001945/11/01/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202223/5** dated **08/07/2022** against advance authorization No. **3111000421 dated 23/06/2021**, 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.
Levostin (Levofloxacin 10 percent w/v and colistin sulphate 1.5 percent w/v oral liquid) (Net Weight of Import Item is 0.015 kgs per liter in the export item)	10000 Litres	1	COLISTIN SULPHATE	150 kg.

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

Case No.	137 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	GMFC LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005667AM23
RA File Number	09AX04000895 AM23
Licence No and Date	0911004300/11/01/2023

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.
Diisopropyl azodicarboxylate (Net content of Isopropyl chloroformate is 29400 Kgs)	1 kg.	1	Isopropyl chloroformate	1.347 kg.

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

Case No.	138 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005679AM23
RA File Number	08AX04001685 AM23
Licence No and Date	0811006983/11/01/2023
Norms Committee Decision:	
Deferred for the comments of TE. Also submit shipping bill and bill of entry of the export products.	

Case No.	139 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005687AM23
RA File Number	31AX04000281 AM23
Licence No and Date	3111001952/12/01/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm: -	
1. Process details given in Attachment 1 is for 83.33 % w/w, not matching with export item. 2. Copy of Master-Batch Formula may be furnished.	

3. Also submit shipping bill and bill of entry of the export products.

Case No.	140 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005707AM23
RA File Number	07AX04001495 AM23
Licence No and Date	0711006134/13/01/2023

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.
Valproate Sodium Injection 100mg/mL, 5ml(Valproate Sodium Injection 100mg/mL, 5ml Vial - filled with 500mg of Valporate Sodium as bulk drug is filled in 5mL Vial and capped with 20mm chlorobutyle Rubber Stopper)	272727.0 Numbers	1	WPS S10-F451 4432/50G B2-40 WESTARRS1m/PK (20mm Chlorobutyle Rubber Stopper)	Relevant as per Packing Policy.

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

Case No.	141 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005711AM23
RA File Number	34AX04000943 AM23
Licence No and Date	3411003244/13/01/2023
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Feb/202223/20** dated **24/02/2023** against advance authorization **No. 3411000043** dated **17/02/2021**, 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.
3-TRIFLUOROMETHYL ACETO PHENONE	1 kg.	1	Benzo Trifluoride	1.26 kg.
		2	Toluene	0.1075 kg.
		3	Caustic Soda Lye 47 PERCENT	0.50 kg.
		4	Acetaldoxime 50 PERCENT Min Solution in Water	0.951 kg.
		5	Soda Ash	0.005
		6	Nitric Acid 72 Percent	Not allowed

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

Case No.	142 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005714AM23
RA File Number	04AX04000873 AM23
Licence No and Date	0411004751/13/01/2023

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.
IBUPROFEN	1 kg.	1	Isobutyl Acetophenone	1.11 kg.
		2	Sodium Metal	0.235 kg.
		3	Monochloro Acetic Acid	0.919 kg.
		4	Isopropyl Alcohol	0.50 kg.
		5	Sodium Dichromate	0.630 kg.

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

Case No.	143 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005715AM23
RA File Number	04AX04000871 AM23
Licence No and Date	0411004703/13/01/2023

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.
IBUPROFEN	1 kg.	1	Isobutyl Acetophenone	1.11 kg.
		2	Sodium Metal	0.235 kg.
		3	Monochloro Acetic Acid	0.919 kg.

		4	Isopropyl Alcohol	0.50 kg.
		5	Sodium Dichromate	0.630 kg.

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

Case No.	144 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005735AM23
RA File Number	03AX04005047 AM23
Licence No and Date	0311020724/16/01/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202223/22** dated **24/03/2023** against advance authorization **No. 0311018957 dated 31/10/2022**, 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. (in mg.)
GLIPIZIDE EXTENDED RELEASE TABLETS 10 MG. Each tablet contains (i) Glipizide USP- 10 mg(ii) Eastman (TM)CelluloseAcetate(CA398-10NF/EP)- 29.70mg(iii) SentryPolyoxWSR N80FPNF-178.10 mg(iv)Sentry PolyoxWSR303 NF-100mg.Netcontent (i) 317.12 Kgs (ii) 941.84 Kgs (iii) 5647.85 Kgs (iv) 3171.17 Kgs.)	1 Number	1	GLIPIZIDE USP	10.20
		2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	29.70
		3	SENTRY POLYOX WSR N80 FP NF	178.10
		4	SENTRY POLYOX WSR 303 NF	100.00
GLIPIZIDE EXTENDED	1 Number	5	GLIPIZIDE USP	5.10

RELEASE TABLETS 5 MG. Each tablet contains (i) Glipizide USP- 5 mg(ii) Eastman (TMCelluloseAcetate(CA398-10NF/EP)- 20.40mg(iii) SentryPolyoxWSR N80FPNF- 89.05 mg(iv)Sentry PolyoxWSR303 NF-50mg.Net content (i) 256.76 Kgs (ii) 1047.57 Kgs (iii) 4572.84 Kgs (iv) 2567.57 Kgs.)		6	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	20.40
		7	SENTRY POLYOX WSR N80 FP NF	89.05
		8	SENTRY POLYOX WSR 303 NF	50.00
GLIPIZIDE EXTENDED RELEASE TABLETS 2.5 MG. Each tablet contains (i) Glipizide USP- 2.5 mg(ii) Eastman (TMCellulose 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. Netcontent (i) 101.80 Kgs (ii) 830.70 Kgs (iii) 3626.18 Kgs (iv) 2036.04 Kgs.)	1 Number	9	GLIPIZIDE USP	2.55
		10	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	20.40
		11	SENTRY POLYOX WSR N80 FP NF	89.05
		12	SENTRY POLYOX WSR 303 NF	50.00

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

Case No.	145 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005741AM23
RA File Number	07AX04001550 AM23
Licence No and Date	0711006194/16/01/2023
Norms Committee Decision:	
Deferred for the comments of TE.Also submit shipping bill and bill of entry of the export products.	

Case No.	146 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	MICRO LABS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023													
HQ File Number	HQRNORM APPLY 00005743AM23													
RA File Number	07AX04001552 AM23													
Licence No and Date	0711006196/16/01/2023													
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Feb/202223/20 dated 24/02/2023 against advance authorization No. 0711005409 dated 06/10/2022, 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:- <table border="1" data-bbox="197 750 1428 1158"> <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>PREMIX OF NIFUROXAZIDE ((Each gm of Premix Contains Nifuroxazide BP 0.552 gm) Nifuroxazide Net Content is 3477.60 kg))</td> <td>6300 kg.</td> <td>1</td> <td>NIFUROXAZIDE BP/EP</td> <td>3512.376 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.	PREMIX OF NIFUROXAZIDE ((Each gm of Premix Contains Nifuroxazide BP 0.552 gm) Nifuroxazide Net Content is 3477.60 kg))	6300 kg.	1	NIFUROXAZIDE BP/EP	3512.376 kg
Export Product	Qty.	Sl. No.	Import Items	Qty.										
PREMIX OF NIFUROXAZIDE ((Each gm of Premix Contains Nifuroxazide BP 0.552 gm) Nifuroxazide Net Content is 3477.60 kg))	6300 kg.	1	NIFUROXAZIDE BP/EP	3512.376 kg										

Case No.	147 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005744AM23
RA File Number	07AX04001546 AM23
Licence No and Date	0711006197/16/01/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Feb/202223/20 dated 24/02/2023 against advance authorization No. 0811006214 dated 10/10/2022, 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.
DOXYCYCLINE 100MG DISPERSIBLE TABLETS ((equivalent to anhydrous doxycycline 100mg) USP/IP (600.00 KG))	1 Number	1	DOXYCYCLINE MONOHYDRATE U.S.P/B.P.	102.908 mg.
RA concerned may take further necessary action as per above decision of NC				

Case No.	148 / NC/3/MEET/Apr/202324/1
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005745AM23
RA File Number	07AX04001545 AM23
Licence No and Date	0711006198/16/01/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. 7/AM-18** dated **24/08/2018** against advance authorization **No. 0710109368 dated 04/02/2016**, 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.
AMOXICILLIN 125MG + FLUCLOXACILLIN 125MG/5ML ORAL SUSPENSION 100ML BOTTLES(AMOXICILLIN 125MG + FLUCLOXACILLIN 125MG/5ML ORAL SUSPENSION 100ML BOTTLES 250.00 KG)	1 No. bottle	1	AMOXICILLIN TRIHYDRATE BP/EP/USP/IP	3012.83 mg/bottle
		2	FLUCLOXACILLIN SODIUM BP/EP/USP/IP	2856.33 mg/bottle
AMOXICILLIN 250MG + FLUCLOXACILLIN 250MG	1 No.3 Capsules		AMOXICILLIN TRIHYDRATE BP/EP/USP/IP	292.68 mg/capsule

CAPSULES(AMOXICILLIN 250MG + FLUCLOXACILLIN 250MG CAPSULES - 2499.980 KG)		4	FLUCLOXACILLIN SODIUM BP/EP/USP/IP	277.47 mg/capsule
RA concerned may take further necessary action as per above decision of NC				

Case No.	149 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	PRACHI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005760AM23
RA File Number	03AX04005177 AM23
Licence No and Date	0311020750/16/01/2023
Norms Committee Decision:	
Deferred for the comments of TE.Also submit shipping bill and bill of entry of the export products.	

Case No.	150 / NC/3/MEET/Apr/202324/1
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202324/ 1 and 28/04/2023
HQ File Number	HQRNORM APPLY 00005762AM23
RA File Number	08AX04001684 AM23
Licence No and Date	0811007029/16/01/2023
Norms Committee Decision:	
Deferred for the comments of TE.Also submit shipping bill and bill of entry of the export products.	