



Government of India
Ministry of Commerce and Industry
Department of Commerce

DIRECTORATE GENERAL OF FOREIGN TRADE
(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Apr/202223/1

DATED: 29/04/2022

Please 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/202223/1 dated 29/04/2022 of Norms Committee - III for the year 2022-23 was held on 29/04/2022 under the Chairmanship of Amiya Chandra, Additional DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2015-20.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	AJAY KUMAR, Deputy Director	Directorate General of Foreign Trade, Delhi
2	SHAISH KUMAR, Technical Authority	Technical Consultant, DGFT
3	DINESHNARAIN MATHUR, Technical Authority	Technical Consultant, DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022			
HQ File Number	HQRNORM APPLY 00235235AM22			
RA File Number	092404000488 AM21			
Licence No and Date	0911000087/null			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
LEVETIRACETAM	1 kg	1	S(+)-2-Amino Butyramide HCL	0.95 kg
		2	Activated Carbon (Carbon Enoanticromos)	0.012 kg
		3	Methylene chloride (MDC)	2.26 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	2 / NC/3/MEET/Apr/202223/1			
Case Status	Case Approved			
Party Name	INCHEM LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022			
HQ File Number	HQRNORM REVIW00229507AM22			
RA File Number	092404000105 AM13			
Licence No and Date	0910052851/31/05/2012			
Norms Committee Decision:				
The Committee considered the request of firm for enhancement of norms and it was decided to revise adhoc norms as under:				
Export Product	Qty.	Sl. No.	Import Items	Qty.
RACTOPAMINE HCL (for Veterinary use)	1 kg	1	(RS)4-(2 AMINO-1-HYDROXY ETHYL) PHENOL HCL	1.063 kg

		2	4(4-HYDROXY PHENYL)-2-BUTANONE	0.978 kg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	3 / NC/3/MEET/Apr/202223/1
Case Status	Case Rejected
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00219542AM22
RA File Number	092404000239 AM13
Licence No and Date	0910053490/14/08/2012
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was observed that the firm has not provided any technical data in support of its request. Hence, it was decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	4 / NC/3/MEET/Apr/202223/1
Case Status	Case Rejected
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00229497AM22
RA File Number	092404000374 AM15
Licence No and Date	0910061119/17/10/2014
Norms Committee Decision: The Committee considered the request of firm for allowing import item No. 2 – Nitro Methane and it was observed that import item No 2 – Nitro Methane was earlier shown as reactant and now the firm is claiming that it is solvent. In view of above discrepancy, the Committee reject the request of firm, decided not to allow import item No. 2 - Nitro Methane. RA concerned may take further necessary action as per above decision of NC.	

Case No.	5 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00285240AM22
RA File Number	039404000164 AM16
Licence No and Date	0310796757/23/06/2015

Norms Committee Decision:

The Committee considered the request of firm for enhancement of norms and it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
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.	6 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	U SQUARE LIFESCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00268752AM22
RA File Number	082404000306 AM16
Licence No and Date	0810136712/11/12/2015

Norms Committee Decision:

The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm:

COA of import item from foreign supplier for the relevant import for this Advance Authorization.

Case No.	7 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved

Party Name	KOPRAN RESEARCH LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022			
HQ File Number	HQRNORM REVIW00273961AM22			
RA File Number	039404001110 AM16			
Licence No and Date	0310806126/12/07/2016			
Norms Committee Decision:				
The Committee considered the request of firm for enhancement of norms and it was decided to revise adhoc norms as under:				
Export product	Qty.	Sl. No.	Import items	Qty.
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.	8 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00349952AM22
RA File Number	522404000042 AM17
Licence No and Date	5210042032/30/09/2016
Norms Committee Decision:	
The Committee considered the request of firm for enhancement of 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 alongwith 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.	
End use of export product.	

Case No.	9 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00342368AM22
RA File Number	039404001099 AM17
Licence No and Date	0310811662/07/03/2017
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights alongwith 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. Recovery of solvents. Production / Consumption data for the year 2017-18 duly certified by GST Authorities.	

Case No.	10 / NC/3/MEET/Apr/202223/1
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00285059AM22
RA File Number	039404000575 AM18
Licence No and Date	0310816510/25/10/2017
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was observed that the firm has not provided any technical data in support of its request. Hence, it was decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	11 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SYNNAT PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00354679AM22

RA File Number	022404000188 AM18
Licence No and Date	0210208260/07/03/2018
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. COA of import item from foreign supplier for the relevant import. Past Production / Consumption data for last three years duly certified by Central Taxes & GST Authorities.	

Case No.	12 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	AVA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00266331AM22
RA File Number	039404000146 AM19
Licence No and Date	0310821149/22/05/2018
Norms Committee Decision: The Committee considered the request of firm for enhancement of 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 alongwith 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. Production / Consumption data for the year 2018-19 duly certified by GST Authorities.	

Case No.	13 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	KUSUMA PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00279795AM22
RA File Number	039404000236 AM19
Licence No and Date	0310822077/02/07/2018
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following	

information / documents from the firm:

i. COA of import item (from foreign supplier) and export product indicating percentage purity and impurity profile.

Case No.	14 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	KUSUMA PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00280735AM22
RA File Number	039404000237 AM19
Licence No and Date	0310822078/02/07/2018

Norms Committee Decision:

The Committee considered the request of firm for enhancement of norms and it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
SACCHARIN POWDER (PURE/AR) (DENTAL GRADE) (Not less than 98% purity)	1 kg	1	SODIUM SACCHARIN	1.38 kg

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

Case No.	15 / NC/3/MEET/Apr/202223/1
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00285187AM22
RA File Number	039404000541 AM19
Licence No and Date	0310824058/28/09/2018

Norms Committee Decision:

The Committee considered the request of firm for enhancement of norms and it was observed that the firm has not

provided any technical data in support of its request. Hence, it was decided to **reject** the case maintaining the status quo.

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

Case No.	16 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SYNNAT PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00354757AM22
RA File Number	022404000113 AM19
Licence No and Date	0210208784/01/11/2018
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. COA of import item from foreign supplier for the relevant import. Past Production / Consumption data for last three years duly certified by Central Taxes & GST Authorities.	

Case No.	17 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	U SQUARE LIFESCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00296493AM22
RA File Number	082404000329 AM19
Licence No and Date	0810144243/07/01/2019
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: COA of import item from foreign supplier for the relevant import for this Advance Authorization.	

Case No.	18 / NC/3/MEET/Apr/202223/1
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00292348AM22
RA File Number	039404000922 AM19
Licence No and Date	0310826698/30/01/2019
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was observed that the firm has not provided any technical data in support of its request. Hence, it was decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	19 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SYNNAT PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00354703AM22
RA File Number	022404000173 AM19
Licence No and Date	0210209010/26/02/2019
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. COA of import item from foreign supplier for the relevant import. Past Production / Consumption data for last three years duly certified by Central Taxes & GST Authorities.	

Case No.	20 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	DIPS BIOSCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00340357AM22
RA File Number	039404000199 AM20
Licence No and Date	0310829573/12/06/2019
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify 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	AGROZEN FORTE 23.6gm Sachet. Each sachet contains - -(a) Diminazene Diaceturate BP Vet 10.5gm, (b) Vitamin B12 BP 10.0mg, (c) Vitamin B6 BP 50.0mg, (d) Excipients.. q.s.= 100000 Sachets (10 Sachets in each Box)	10000 Boxes	1	CYANOCOBALAMIN BP (VITAMIN B12)	4.39 kg
2	TRYPTAZENE PLUS 23.6gm Sachet contains - (a) Diminazene Diaceturate BP Vet 10.5gm, (b) Vitamin B12 BP 15.0mg, (c) Vitamin B6 BP 60.0mg, (d) Vitamin B1 BP 100mg (e) Vitamin B2 BP 1.0mg, (f) Vitamin PP (Niacin BP) 100.0mg (g) Excipients.. QS...23.6gm = 100000 Sachets (10 Sachets in each Box)	10000 Boxes			
3	VETOZEN PLUS 23.6gm Sachet. Each sachet contains - -(a) Diminazene Diaceturate BP Vet 10.5gm, (b) Vitamin B12 BP 10.0mg, (c) Excipients.. q.s.= 100000 Sachets (10 Sachets in each Box)	10000 Boxes			
4	APPYVET 23.6gm Sachet. Each Sachet contains - -(a) Diminazene Diaceturate BP Vet 10.5gm, (b) Vitamin B12 BP 10.0mg, (c) Excipients.. q.s. = 84730 Sachets (10 Sachets in each Box)	8473 Boxes			

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

Case No.	21 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	TITAN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	018205000340AM20
RA File Number	039504000318 AM20
Licence No and Date	0310830043/03/07/2019
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm to attend <u>Personal Hearing</u> before Norms Committee alongwith following documents / information: i. Import item No.2 is not matching with Master Batch Formula. Quantity of import item No. 3 and 4 are not matching with Master Batch Formula and Batch Record.	

Case No.	22 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SYNNAT PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00288853AM22
RA File Number	022404000076 AM20
Licence No and Date	0210209378/16/08/2019
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. COA of import item from foreign supplier for the relevant import. Past Production / Consumption data for last three years duly certified by Central Taxes & GST Authorities.	

Case No.	23 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00348357AM22
RA File Number	052404000683 AM20
Licence No and Date	0510413419/22/01/2020

Norms Committee Decision:

Deferred for comments of Department of Biotechnology (DBT).

Case No.	24 / NC/3/MEET/Apr/202223/1
Case Status	Case Rejected
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	018205001847AM21
RA File Number	052304000050 AM21
Licence No and Date	0510414389/12/06/2020

Norms Committee Decision:

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

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

Case No.	25 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM REVIW00287678AM22
RA File Number	039404000227 AM21
Licence No and Date	0310837081/08/07/2020

Norms Committee Decision:

The Committee considered the request of firm for revision of adhoc norms and it was decided to revise adhoc norms as under:

Sl. No.	Export Product	Qty.
1	Desonide Cream 0.05% 15gm (Net Wt. of Desonide USP Micronised (Sicor) is 0.188 Kgs)	1 Number
2	Desonide Cream 0.05% 60gm (Net Wt. of Desonide USP Micronised (Sicor) is 0.750 Kgs)	1 Number
3	Desonide Lotion 0.05% 59ml (Net Wt. of Desonide USP Micronised (Sicor) is 0.738 Kgs)	1 Number

4	Desonide Lotion 0.05% 118ml (Net Wt. of Desonide USP Micronised (Sicor) is 1.475 Kgs)	1 Number
5	Desonide Ointment 0.05% 15gm (Net Wt. of Desonide USP Micronised (Sicor) is 0.188 Kgs)	1 Number
6	Desonide Ointment 0.05% 60gm (Net Wt. of Desonide USP Micronised (Sicor) is 0.750 Kgs)	1 Number

Sl. No.	Import Items	For the Export of 1 No. Pack					
		0.05% 15 gm pack	0.05% 60 gm pack	0.05% 59 ml pack	0.05% 118 ml pack	0.05% 15 gm pack	0.05% 60 gm pack
1	Desonide USP Micronised (Sicor)	0.00765 gm	0.0306 gm	0.0301 gm	0.0602 gm	0.00765 gm	0.0306 gm

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

Case No.	26 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	BIOLOGICAL E. LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	018205001585AM21
RA File Number	092404000253 AM21
Licence No and Date	0910069107/27/08/2020

Norms Committee Decision:

The Committee considered the case as per agenda and on the basis of comments furnished by Department of Biotechnology vide e-mail dated 12.01.2022, the Committee decided to ratify adhoc norms for export product DIPHTHERIA AND TETANUS (DT) / TETANUS AND DIPHTHERIA (TD) VACCINE ADSORBED 10ML 20 DOSES – 50000 kg, allowing wastage as applied by the firm for import item No. 1 to 9, and 13 to 15, however for import item No. 10 to 12, only 2% wastage is allowed.

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

Case No.	27 / NC/3/MEET/Apr/202223/1
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Case Status	Case Approved			
Party Name	ZENITH DYEINTERMEDIATES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022			
HQ File Number	HQRNORM REVIW00286536AM22			
RA File Number	039504000328 AM21			
Licence No and Date	0310838112/07/09/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify norms under Para 4.07 of HBP Vol. as per details given below or as applied by the firm, whichever is less:				

Case No.	28 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	018205001858AM21
RA File Number	039404000644 AM21
Licence No and Date	0310839600/19/11/2020
Norms Committee Decision:	
The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm:	
i. Copy of 4.07 application having copy of Advance Authorization alongwith complete technical details as per Annexure to Appendix 4E.	

Case No.	29 / NC/3/MEET/Apr/202223/1			
Case Status	Case Deferred			
Party Name	TENSHI KAIZEN PRIVATE LIMITED			

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	018205001859AM21
RA File Number	072404000225 AM21
Licence No and Date	0710117295/19/11/2020
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. Copy of 4.07 application having copy of Advance Authorization alongwith complete technical details as per Annexure to Appendix 4E.	

Case No.	30 / NC/3/MEET/Apr/202223/1													
Case Status	Case Approved													
Party Name	ZENTIVA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022													
HQ File Number	018205001860AM21													
RA File Number	039504000530 AM21													
Licence No and Date	0310839621/19/11/2020													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Feb/202122/14 dated 21/02/2022 against advance authorization No. 0311004568 dt. 13-06-2021 , it was decided to ratify 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>CLOPIDOGREL 75MG TABLETS Clopidogrel Zentiva / Clopidogrel Almus / Trombex (Each Tablet contain 75mg of CLOPIDOGREL BISULFATE FORM II)</td><td>1 Number</td><td>1</td><td>CLOPIDOGREL BISULFATE FORM II</td><td>Net content in Export Description + 2%</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	CLOPIDOGREL 75MG TABLETS Clopidogrel Zentiva / Clopidogrel Almus / Trombex (Each Tablet contain 75mg of CLOPIDOGREL BISULFATE FORM II)	1 Number	1	CLOPIDOGREL BISULFATE FORM II	Net content in Export Description + 2%
Export product	Qty.	Sl. No.	Import items	Qty.										
CLOPIDOGREL 75MG TABLETS Clopidogrel Zentiva / Clopidogrel Almus / Trombex (Each Tablet contain 75mg of CLOPIDOGREL BISULFATE FORM II)	1 Number	1	CLOPIDOGREL BISULFATE FORM II	Net content in Export Description + 2%										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	31 / NC/3/MEET/Apr/202223/1
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Case Status	Case Deferred
Party Name	FINE ORGANICS
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	018205001867AM21
RA File Number	052304000296 AM21
Licence No and Date	0510415978/24/11/2020
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. Copy of 4.07 application having copy of Advance Authorization alongwith complete technical details as per Annexure to Appendix 4E.	

Case No.	32 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	018205001869AM21
RA File Number	052404000441 AM21
Licence No and Date	0510415972/24/11/2020
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. Copy of 4.07 application having copy of Advance Authorization alongwith complete technical details as per Annexure to Appendix 4E.	

Case No.	33 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	CENTRIENT PHARMACEUTICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00233450AM22
RA File Number	302404000083 AM21
Licence No and Date	3010105531/25/11/2020
Norms Committee Decision:	

The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm:

- i. **Copy of 4.07 application having copy of Advance Authorization alongwith complete technical details as per Annexure to Appendix 4E.**

Case No.	34 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00233934AM22
RA File Number	072404000233 AM21
Licence No and Date	0710117320/25/11/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **5/82-ALC4/2020 dated 09.10.2020** against advance authorization No. **0710116165 dt. 25.02.2020**, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
REBAMIPIDE TABLETS 100MG [53921569 NO.]	1 Number Tablet	1	REBAMIPIDE	102.00 mg
		2	Ethyl Alcohol 200 Proof (Ethanol)	151.00 mg

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

Case No.	35 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	FINE ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00231954AM22
RA File Number	039404000665 AM21
Licence No and Date	0310839754/26/11/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Jun/202122/2 dated 02/07/2021** against advance authorization No. **0311003756 dt. 12-05-2021**, it was decided to ratify norms under Para 4.07 of HBP 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 Stearyl Lactylate	1 kg	1	Lactic Acid	0.440 kg
		2	Stearic Acid	0.700 kg

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

Case No.	36 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00235232AM22
RA File Number	092404000485 AM21
Licence No and Date	0910069507/26/11/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **5/82-ALC4/2020 dated 09.10.2020** against advance authorization No. **0910067168 dt. 13.02.2019**, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
DARUNAVIR PROPYLENE GLYCOLATE	1 kg	1	(2S,3S)-1,2-Epoxy-3-(Boc-amino)-4-phenylbutane (or) BOC-Epoxyde	0.587 kg
		2	Activated Carbon (Carbon Enoanticromos)	0.100 kg

		3	[3R,3aS,6aR]-3-Hydroxyhexahydrofuro[2,3-b]furan-3-yl succinimidyl carbonate	0.480 kg
		4	Isobutylamine	0.330 kg

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

Case No.	37 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00232802AM22
RA File Number	039504000555 AM21
Licence No and Date	0310839760/26/11/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Jul/202122/4 dated 15/07/2021** against advance authorization No. **0311001140 dt. 21-01-2021**, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
TOLYLTRIAZOLE (GRANULES)	1 kg	1	TOLYLTRIAZOLE	1.005 kg / kg content in the export product

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

Case No.	38 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00235562AM22
RA File Number	342404000231 AM21

Licence No and Date	3410046563/26/11/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 10/82-ALC4/2019 dated 29.11.2019 against advance authorization No. 3410045527 dt. 10.10.2019, it was decided to ratify norms under Para 4.07 of HBP 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 kg	1	BENZENE	0.87 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	39 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	018205001864AM21
RA File Number	039404000659 AM21
Licence No and Date	0310839748/26/11/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. COA and purity of export and import item. ii. Impurity profile in import and export item. iii. Complete process of manufacturing indicating purity achieved at each step. iv. Production / Consumption data duly certified by GST. Justification for 25% wastage.	

Case No.	40 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	VHB MEDI SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	018205001866AM21

RA File Number	039504000553 AM21			
Licence No and Date	0310839755/26/11/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Jan/202021/4 dated 12.02.2021 against advance authorization No. 0310834259 dt. 16.01.2020, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Colistmethate Sodium for injection BP COLISIN-RD 1 MIU((Net content Number of Import item = 8.855 kgs))	115000	1	Colistimethate Sodium Sterile EP	9.027 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	41 / NC/3/MEET/Apr/202223/1			
Case Status	Case Approved			
Party Name	FINE ORGANIC INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022			
HQ File Number	HQRNORM APPLY 00231953AM22			
RA File Number	039404000666 AM21			
Licence No and Date	0310839768/27/11/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 10/82-ALC4/2018 dated 16.10.2018 against advance authorization No. 0310819184 dt. 15.02.2018, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
BEHENAMIDE	1 kg	1	BEHENIC ACID	1.11 kg

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

Case No.	42 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	MALWA OXYGEN & INDUSTRIAL GASES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00235076AM22
RA File Number	562404000035 AM21
Licence No and Date	5610006002/27/11/2020
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. Copy of 4.07 application having copy of Advance Authorization alongwith complete technical details as per Annexure to Appendix 4E.	

Case No.	43 / NC/3/MEET/Apr/202223/1													
Case Status	Case Approved													
Party Name	CLARIANT INDIA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022													
HQ File Number	HQRNORM APPLY 00233237AM22													
RA File Number	039404000660 AM21													
Licence No and Date	0310839769/27/11/2020													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 3/82-ALC4/2019 dated 05.07.2019 against advance authorization No. 0310825405 dt. 04.12.2018 , it was decided to ratify 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 rowspan="2">EHT (ETHYL HEXYL TRIAZONE) / ETONE</td><td rowspan="2">1 kg</td><td>1</td><td>PARA NITRO BENZOIC ACID (PNBA)</td><td>1.034 kg</td></tr><tr><td>2</td><td>PERCHLORO ETHYLENE (PCE)</td><td>0.606 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	EHT (ETHYL HEXYL TRIAZONE) / ETONE	1 kg	1	PARA NITRO BENZOIC ACID (PNBA)	1.034 kg	2	PERCHLORO ETHYLENE (PCE)	0.606 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
EHT (ETHYL HEXYL TRIAZONE) / ETONE	1 kg	1	PARA NITRO BENZOIC ACID (PNBA)	1.034 kg										
		2	PERCHLORO ETHYLENE (PCE)	0.606 kg										

		3	ACETO NITRILE	1.30 kg
		4	CYANURIC CHLORIDE	0.640 kg

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

Case No.	44 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	PARAMOUNT AROMACHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00233238AM22
RA File Number	052404000444 AM21
Licence No and Date	0510415997/27/11/2020
Norms Committee Decision:	
The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm:	
i. Copy of 4.07 application having copy of Advance Authorization alongwith complete technical details as per Annexure to Appendix 4E.	

Case No.	45 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00234858AM22
RA File Number	092404000482 AM21
Licence No and Date	0910069522/27/11/2020
Norms Committee Decision:	
The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm:	
i. Copy of 4.07 application having copy of Advance Authorization alongwith complete technical details as per Annexure to Appendix 4E.	

Case No.	46 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00117698AM21
RA File Number	03AA04033579 AM21
Licence No and Date	0311002962/31/03/2021
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. Copy of 4.07 application having copy of Advance Authorization alongwith complete technical details as per Annexure to Appendix 4E.	

Case No.	47 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00131778AM22
RA File Number	34AA04004352 AM22
Licence No and Date	3411000801/06/07/2021
Norms Committee Decision: The Committee considered the case as per agenda and reply furnished by the firm on DGFT portal and it was observed that the firm did not submit proper reply. Hence, it was decided to again call for following information / documents from the firm: i. Commercial value of Residue and Low & High Boiler. Production / Consumption data for last one year duly certified by GST	

Case No.	48 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SUVEN PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00133260AM22
RA File Number	09AA04007209 AM22
Licence No and Date	0911001161/07/07/2021

Norms Committee Decision:
Deferred for comments of TE.

Case No.	49 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SUVEN PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00133263AM22
RA File Number	09AA04003483 AM22
Licence No and Date	0911001162/07/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	50 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00133324AM22
RA File Number	34AA04004084 AM22
Licence No and Date	3411000813/07/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	51 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00134044AM22
RA File Number	31AA04019601 AM22
Licence No and Date	3111000445/08/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Catalogue of import item No. 4 - Morpholine catalyst.	

- ii. **Whether Hydrogen will be imported or will it be procured indigenously.**
- iii. **Production / Consumption data for last year duly certified by GST Authorities.**
- iv. **Percentage yield of reaction.**
- v. **Decision of similar case earlier approved by NC-3.**

Case No.	52 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00134197AM22
RA File Number	03AA04035672 AM22
Licence No and Date	0311005214/08/07/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name. ii. Details of Packaging Material may be furnished. iii. Copy of Master Batch Formula for all export items indicating net content of inputs in each export.	

Case No.	53 / NC/3/MEET/Apr/202223/1				
Case Status	Case Approved				
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022				
HQ File Number	HQRNORM APPLY 00135169AM22				
RA File Number	03AA04043282 AM22				
Licence No and Date	0311005238/09/07/2021				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					

(QEK31)		2	Ethyl Pyruvate	0.676 kg
		3	Bromine	1.143 kg
		4	Dichloromethane	Not allowed, as it is being reused
		5	Acetic acid	Not allowed, as it is being reused

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

Case No.	54 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	CERIGO ADDITIVES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00135220AM22
RA File Number	03AA04027670 AM22
Licence No and Date	0311005241/09/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Percentage yield of reaction at every stage.	

Case No.	55 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00135125AM22
RA File Number	30AA04009718 AM22
Licence No and Date	3011000867/09/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	56 / NC/3/MEET/Apr/202223/1										
Case Status	Case Approved										
Party Name	MANGALAM ORGANICS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022										
HQ File Number	HQRNORM APPLY 00136426AM22										
RA File Number	03AA04000007 AM22										
Licence No and Date	0311005286/11/07/2021										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 4/82-ALC4/2020 dated 18.09.2020 against advance authorization No. 0910065468 dt. 15.09.2017 , it was decided to ratify 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>Camphene</td><td>1 kg</td><td>1</td><td>Alpha Pinene</td><td>1.140 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import items	Qty.	Camphene	1 kg	1	Alpha Pinene	1.140 kg
Export Product	Qty.	Sl. No.	Import items	Qty.							
Camphene	1 kg	1	Alpha Pinene	1.140 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	57 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00136446AM22
RA File Number	07AA04010172 AM22
Licence No and Date	0711001451/11/07/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	58 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00137172AM22
RA File Number	08AA04014354 AM22

Licence No and Date	0811001969/12/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	59 / NC/3/MEET/Apr/202223/1													
Case Status	Case Approved													
Party Name	BIOMATRIX HEALTHCARE PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022													
HQ File Number	HQRNORM APPLY 00137175AM22													
RA File Number	08AA04014083 AM22													
Licence No and Date	0811001973/12/07/2021													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Mar/202122/15 dated 17/03/2022 against advance authorization No. 0811000629 dt. 10-02-2021 , it was decided to ratify 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>Erythromycin Stearate Oral Suspension 250mg/5ml(Each 5ml of reconstituted suspension contains Erythromycin Stearate BP Eq. to Erythromycin 250mg), 100 ml bottle</td><td>628500 Number Bottles</td><td>1</td><td>Erythromycin Stearate BP</td><td>4578.4 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	Erythromycin Stearate Oral Suspension 250mg/5ml(Each 5ml of reconstituted suspension contains Erythromycin Stearate BP Eq. to Erythromycin 250mg), 100 ml bottle	628500 Number Bottles	1	Erythromycin Stearate BP	4578.4 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Erythromycin Stearate Oral Suspension 250mg/5ml(Each 5ml of reconstituted suspension contains Erythromycin Stearate BP Eq. to Erythromycin 250mg), 100 ml bottle	628500 Number Bottles	1	Erythromycin Stearate BP	4578.4 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	60 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00137286AM22
RA File Number	03AA04025361 AM22
Licence No and Date	0311005326/12/07/2021
Norms Committee Decision:	

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

- i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name.
- ii. Details of Packaging Material may be furnished.
- iii. Copy of Master Batch Formula for all export items indicating net content of inputs in each export.

Case No.	61 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00136463AM22
RA File Number	03AA04044012 AM22
Licence No and Date	0311005290/12/07/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Jul/202122/4 dated 15/07/2021** against advance authorization No. **0311004815 dt. 22-06-2021**, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
DORIPENEM STERILE	183 kg	1	MAP METHYL VINYL PHOSPHATE CAS NO 189188383 4R SS 6S 3 DIPHENYLOXY 6 1R HYDROXYETHYL 4 METHYL 7 OXO 1 AZABICYCLO 3 2 0	457.50 kg
		2	DORIPENEM SIDE CHAIN 4 NITROBENZYL 2S 4S 4 ACETYLTIO 2 N SULFAMOYL N TERT BUTOXYCARBONYL AMINO PYRROLIDINE 1 CARBOXYLAT	4450.50 kg

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

Case No.	62 / NC/3/MEET/Apr/202223/1
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Case Status	Case Approved													
Party Name	MANGALAM ORGANICS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022													
HQ File Number	HQRNORM APPLY 00136603AM22													
RA File Number	03AA04022055 AM22													
Licence No and Date	0311005307/12/07/2021													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Feb/202122/14 dated 21/02/2022 against advance authorization No. 0310824148 dt. 03-10-2018 , it was decided to ratify 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">SODIUM ACETATE (TRIHYDRATE)</td><td rowspan="2">1 kg</td><td>1</td><td>ACETIC ACID</td><td>0.463 kg</td></tr><tr><td>2</td><td>CAUSTIC ACID</td><td>0.568 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	SODIUM ACETATE (TRIHYDRATE)	1 kg	1	ACETIC ACID	0.463 kg	2	CAUSTIC ACID	0.568 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
SODIUM ACETATE (TRIHYDRATE)	1 kg	1	ACETIC ACID	0.463 kg										
		2	CAUSTIC ACID	0.568 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	63 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00136846AM22
RA File Number	34AA04005040 AM22
Licence No and Date	3411000829/12/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	64 / NC/3/MEET/Apr/202223/1			
Case Status	Case Deferred			
Party Name	SUDEEP PHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022			
HQ File Number	HQRNORM APPLY 00137048AM22			

RA File Number	34AA04005105 AM22
Licence No and Date	3411000838/12/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	65 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00138116AM22
RA File Number	26AA04002063 AM22
Licence No and Date	2611000198/13/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	66 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00138657AM22
RA File Number	03AA04047965 AM22
Licence No and Date	0311005362/14/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	67 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00139912AM22
RA File Number	03AA04027532 AM22
Licence No and Date	0311005407/15/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	

- i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name.
- ii. Details of Packaging Material may be furnished.
- iii. Copy of Master Batch Formula for all export items indicating net content of inputs in each export.

Case No.	68 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	ELIXIR PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00141649AM22
RA File Number	08AA04016381 AM22
Licence No and Date	0811002031/19/07/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **10/82-ALC4/2018 dated 16.10.2018** against advance authorization No. **0810142240 dt. 26.03.2018**, it was decided to ratify norms under Para 4.07 of HBP 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-ISOBUTYL GLUTARIC ACID (CMH DIACID)	1 kg	1	ISOVALERALDEHYDE	0.6068 kg
		2	ETHYL CYANOACETATE	0.7814 kg
		3	DIETHYL MALONATE	0.90 kg

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

Case No.	69 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00143189AM22
RA File Number	52AA04009806 AM22
Licence No and	5211001019/20/07/2021

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 5/82-ALC4/2020 dated 09.10.2020 against advance authorization No. 0310834879 dt. 17.02.2020, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
METHYL PARABEN	1 kg	1	PARA HYDROXY BENZOIC ACID	0.969 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	70 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00143025AM22
RA File Number	07AA04016475 AM22
Licence No and Date	0711001517/20/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	71 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00143924AM22
RA File Number	07AA04016516 AM22
Licence No and Date	0711001521/21/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	72 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00144650AM22
RA File Number	07AA04016659 AM22
Licence No and Date	0711001528/22/07/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
CYCLOBENZAPRINE HCL(USP)	1 kg	1	1 BROMO 3 CHLORO PROPANE	0.95 kg
		2	TETRA HYDRO FURAN	0.25 kg
		3	ACETONE	0.75 kg

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

Case No.	73 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00144695AM22
RA File Number	07AA04016662 AM22
Licence No and Date	0711001530/22/07/2021

Norms Committee Decision:

Deferred for comments of TE.

Case No.	74 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred

Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00145072AM22
RA File Number	05AA04057335 AM22
Licence No and Date	0511003777/22/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	75 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	DIAMINES AND CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00145203AM22
RA File Number	34AA04005573 AM22
Licence No and Date	3411000885/22/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	76 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00145220AM22
RA File Number	34AA04004907 AM22
Licence No and Date	3411000793/22/07/2021
Norms Committee Decision:	
The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. Item of import is Propylene, while material balance is given for raw material Benzene. Please give material balance from Propylene.	

Case No.	77 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	MERIDIAN ENTERPRISES PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022

and Date	
HQ File Number	HQRNORM APPLY 00145626AM22
RA File Number	03AA04051822 AM22
Licence No and Date	0311005561/23/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	78 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00146194AM22
RA File Number	03AA04051472 AM22
Licence No and Date	0311005584/23/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	79 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00145549AM22
RA File Number	09AA04008489 AM22
Licence No and Date	0911001257/23/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Oct/202122/10 dated 12/11/2021 against advance authorization No. 0911000180 dt. 11-01-2021 , it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

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

Case No.	80 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00146728AM22
RA File Number	03AA04046766 AM22
Licence No and Date	0311005598/24/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	81 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00146729AM22
RA File Number	03AA04029068 AM22
Licence No and Date	0311005599/24/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	82 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00146743AM22
RA File Number	03AA04045550 AM22
Licence No and Date	0311005604/25/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Export product	Qty.	Sl. No.	Import items	Qty.
DINONYLATED DIPHENYLAMINE (YALUB DND)	1 kg	1	DIPHENYLAMINE	0.4134 kg
		2	NONENE	0.4 kg
		3	ACTIVATED CLAY	0.05 kg

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

Case No.	83 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00147236AM22
RA File Number	34AA04005732 AM22
Licence No and Date	3411000898/26/07/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Oct/202122/10 dated 12/11/2021** against advance authorization No. **0311000408 dt. 28-12-2020**, it was decided to ratify 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	Ramilich / Ramilich Comp / Ramipril HCT ZT/ZTV 5-12.5mg (Net Wt. Hydrochlorothiazide 250.000 KGS)	1 Number	1	Hydrochlorothiazide	12.75 mg / Tablet
2	Ramilich / Ramilich Comp / Ramipril HCT ZT/ZTV 2.5-12.5mg (Net Wt. Hydrochlorothiazide 223.650 KGS)	1 Number	1	Hydrochlorothiazide	12.75 mg / Tablet
3	Ramilich / Ramilich Comp / Ramipril HCT ZT/ZTV 5-25mg	1 Number	1	Hydrochlorothiazide	25.50 mg / Tablet

	(Net Wt. Hydrochlorothiazide 535.00 KGS)				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	84 / NC/3/MEET/Apr/202223/1			
Case Status	Case Approved			
Party Name	CONNEX PHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022			
HQ File Number	HQRNORM APPLY 00147368AM22			
RA File Number	26AA04002378 AM22			
Licence No and Date	2611000203/26/07/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 10/82-ALC4/2018 dated 16.10.2018 against advance authorization No. 3410043944 dt. 08.03.2018 , it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

Case No.	85 / NC/3/MEET/Apr/202223/1				
Case Status	Case Deferred				
Party Name	SYNOKEM PHARMACEUTICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022				
HQ File Number	HQRNORM APPLY 00147457AM22				
RA File Number	05AA04059070 AM22				
Licence No and Date	0511003826/26/07/2021				

Norms Committee Decision:
Deferred for comments of TE.

Case No.	86 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00148387AM22
RA File Number	52AA04010429 AM22
Licence No and Date	5211001058/27/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	87 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00148419AM22
RA File Number	31AA04021097 AM22
Licence No and Date	3111000476/27/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	88 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00148633AM22
RA File Number	07AA04017970 AM22
Licence No and Date	0711001564/27/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Export product	Qty.	Sl. No.	Import items	Qty.
TRIMIPRAMINE MESYLATE (USP/EP)	1 kg	1	IMINODIBENZYL	0.72 kg
		2	1 BROMO 3 CHLORO 2 METHYL PROPANE	0.53 kg
		3	ACETONE	1.00 kg

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

Case No.	89 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00148635AM22
RA File Number	07AA04017973 AM22
Licence No and Date	0711001565/27/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	90 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ZEE LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00149067AM22
RA File Number	05AA04057371 AM22
Licence No and Date	0511003868/28/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	91 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022													
HQ File Number	HQRNORM APPLY 00149310AM22													
RA File Number	05AA04061858 AM22													
Licence No and Date	0511003876/28/07/2021													
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Oct/202122/10 dated 12/11/2021 against advance authorization No. 0511000307 dt. 21-12-2020, it was decided to ratify 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>Inokain Eye Drops 0.4 Percent 5ml</td> <td>1 Vial</td> <td>1</td> <td>Benoxinate HCL</td> <td>20.4 mg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export product	Qty.	Sl. No.	Import items	Qty.	Inokain Eye Drops 0.4 Percent 5ml	1 Vial	1	Benoxinate HCL	20.4 mg
Export product	Qty.	Sl. No.	Import items	Qty.										
Inokain Eye Drops 0.4 Percent 5ml	1 Vial	1	Benoxinate HCL	20.4 mg										

Case No.	92 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00150128AM22
RA File Number	03AA04054005 AM22
Licence No and Date	0311005722/29/07/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Overall yield of 47% is low. Please furnish yield at every stage of reaction and justification for the same. ii. Appendix 11 A seems to be wrong. Since total consumption shown is 7.315 MT, while it should be 410 MT. Please clarify. Production / Consumption data duly certified by GST.	

Case No.	93 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	RAJASTHAN ANTIBIOTICS LTD

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00150875AM22
RA File Number	05AA04055660 AM22
Licence No and Date	0511003910/30/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	94 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	PMC RUBBER CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00272783AM22
RA File Number	02AA04035173 AM22
Licence No and Date	0211001583/02/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	95 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00272834AM22
RA File Number	03AA04014502 AM22
Licence No and Date	0311009117/02/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	96 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00272951AM22
RA File Number	03AA04014150 AM22
Licence No and Date	0311009127/02/12/2021
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	97 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00272165AM22
RA File Number	03AA040124486 AM22
Licence No and Date	0311009090/02/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. COA and purity of export and import item. ii. Impurity profile in import and export item. iii. Complete process of manufacturing indicating purity achieved at each step. iv. Production / Consumption data duly certified by GST. Justification for 25% wastage.	

Case No.	98 / NC/3/MEET/Apr/202223/1										
Case Status	Case Approved										
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022										
HQ File Number	HQRNORM APPLY 00272174AM22										
RA File Number	05AA040106672 AM22										
Licence No and Date	0511006574/02/12/2021										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 7/82-ALC4/2020 dated 04.12.2020 against advance authorization No. 0510415817 dt. 10.11.2020 , it was decided to ratify 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>Nepafenac Ophthalmic Suspension, 0.1 Percent w/v NEPALACT Sterile Eye Drops, 5ml)</td><td>62000 Number</td><td>1</td><td>Nepafenac</td><td>316.2 Gram</td></tr></table>		Export Product	Qty.	Sl. No.	Import items	Qty.	Nepafenac Ophthalmic Suspension, 0.1 Percent w/v NEPALACT Sterile Eye Drops, 5ml)	62000 Number	1	Nepafenac	316.2 Gram
Export Product	Qty.	Sl. No.	Import items	Qty.							
Nepafenac Ophthalmic Suspension, 0.1 Percent w/v NEPALACT Sterile Eye Drops, 5ml)	62000 Number	1	Nepafenac	316.2 Gram							

(PRANAYAM)((Each ml contains Nepafenac 1.0 mg - Equivalent to 310.000 Gram of Bulk Drug))				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	99 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00272724AM22
RA File Number	03AA04012775 AM22
Licence No and Date	0311009114/02/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information/ documents from the firm:	
Stoichiometric balance between import and export on molar basis to arrive at the quantity of raw material asked for.	

Case No.	100 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	AMARA LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00272745AM22
RA File Number	09AA04018011 AM22
Licence No and Date	0911001982/02/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	101 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00274117AM22
RA File Number	09AA04018279 AM22

Licence No and Date	0911001989/03/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Feb/202122/14 dated 21/02/2022 against advance authorization No. 0911000765 dt. 06-05-2021 , it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
PURE L-(-)MENTHOL (Chromatographic Purity NLT 99% by G.C.)	1 kg	1	L-(-)MENTHOL (Purity NMT 97%)	0.99 kg
		2	Toluene	0.99 kg

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

Case No.	102 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00274252AM22
RA File Number	09AA04018274 AM22
Licence No and Date	0911001996/03/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	103 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00274369AM22
RA File Number	09AA04017937 AM22
Licence No and Date	0911001997/03/12/2021
Norms Committee Decision:	

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

Export product	Qty.	Sl. No.	Import items	Qty.
TADALAFIL	1 kg	1	Methyl(1R,3R)-1-(benzol(d)(1,3)dioxol-5-yl)-2-(2-chloroacetyl)-2,3,4,9-tetrahydro-1H-Pyrido(3,4-b)indole-3- carboxylate	1.02 kg

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

Case No.	104 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00273476AM22
RA File Number	34AA04009751 AM22
Licence No and Date	3411001491/03/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	105 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	MAXTAR BIO GENICS
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00273717AM22
RA File Number	05AA040106605 AM22
Licence No and Date	0511006619/03/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Strength of Export Product as per DML.	

Case No.	106 / NC/3/MEET/Apr/202223/1													
Case Status	Case Approved													
Party Name	SENTISS PHARMA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022													
HQ File Number	HQRNORM APPLY 00273970AM22													
RA File Number	05AA040108674 AM22													
Licence No and Date	0511006625/03/12/2021													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Oct/202122/10 dated 12/11/2021 against advance authorization No. 0511000306 dt. 21-12-2020 , it was decided to ratify 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>(Each ml Containing 8 mg Tropicamide)</td><td>1 Number</td><td>1</td><td>Tropicamide</td><td>40.8 mg / 5 ml vial</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	(Each ml Containing 8 mg Tropicamide)	1 Number	1	Tropicamide	40.8 mg / 5 ml vial
Export product	Qty.	Sl. No.	Import items	Qty.										
(Each ml Containing 8 mg Tropicamide)	1 Number	1	Tropicamide	40.8 mg / 5 ml vial										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	107 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	PUNJAB CHEMICALS AND CROP PROTECTION LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00274052AM22
RA File Number	03AA040121338 AM22
Licence No and Date	0311009169/03/12/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	108 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	PUNJAB CHEMICALS AND CROP PROTECTION LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00274069AM22
RA File Number	03AA040121871 AM22

Licence No and Date	0311009171/03/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	109 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	RAKSHIT PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00276086AM22
RA File Number	09AA04016769 AM22
Licence No and Date	0911002001/06/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	110 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00276162AM22
RA File Number	03AA040123869 AM22
Licence No and Date	0311009212/06/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	111 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	YASH RASAYAN & CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00276335AM22
RA File Number	34AX04000001 AM22
Licence No and Date	3411001494/06/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Feb/202122/14 dated 21/02/2022 against advance authorization No. 3410044333 dt. 16-07-2018, it was decided to ratify norms under Para 4.07 of HBP 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 METHOXY BENZOIC ACID	1 kg	1	METHYL SALICYLATE	1.052 kg
		2	DIMETHYL SULPHATE	0.8717 kg

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

Case No.	112 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00276913AM22
RA File Number	05AA040105427 AM22
Licence No and Date	0511006662/06/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	113 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00276997AM22
RA File Number	30AX04000001 AM22
Licence No and Date	3011001471/06/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	114 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred

Party Name	AURA PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00277561AM22
RA File Number	03AA040123116 AM22
Licence No and Date	0311009243/07/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	115 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00277912AM22
RA File Number	05AA040108247 AM22
Licence No and Date	0511006681/07/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	116 / NC/3/MEET/Apr/202223/1			
Case Status	Case Approved			
Party Name	SENTISS PHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022			
HQ File Number	HQRNORM APPLY 00277924AM22			
RA File Number	05AX04000035 AM22			
Licence No and Date	0511006685/07/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

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

Case No.	117 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00277929AM22
RA File Number	05AX04000024 AM22
Licence No and Date	0511006688/07/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **2/82-ALC4/2020 dated 10.07.2020** against advance authorization No. **0510411666 dt. 28.08.2019**, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
TOBRISS (TOBRAMYCIN 0.3 PERCENT) EYE DROPS 5 ML VIAL	1 Vial	1	Tobramycin Sulphate	19.057 mg/ Vial

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

Case No.	118 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00277999AM22
RA File Number	03AX04000024 AM22
Licence No and Date	0311009262/07/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Oct/202122/10 dated 12/11/2021** against advance authorization No. **0311000408 dt. 28-12-2020**, it was decided to ratify 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	Ramilich / Ramilich Comp / Ramipril HCT ZT/ZTV 5-12.5mg, (Net Wt. Hydrochlorothiazide 125.00 KGS)((Net Wt. Ramipril 50.00 KGS))	1 Number	1	Hydrochlorothiazide	12.75 mg / Tablet
			2	Ramipril	5.10 mg
2	Ramilich / Ramilich Comp / Ramipril HCT ZT/ZTV 2.5-12.5mg (Net Wt. Hydrochlorothiazide 125.00 KGS)((Net Wt. Ramipril 25.00 KGS))	1 Number	1	Hydrochlorothiazide	12.75 mg / Tablet
			2	Ramipril	2.55 mg
3	Ramilich / Ramilich Comp / Ramipril HCT ZT/ZTV 5-25mg (Net Wt. Hydrochlorothiazide 750.00 KGS)((Net Wt. Ramipril 150.00 KGS))	1 Number	1	Hydrochlorothiazide	25.50 mg / Tablet
			2	Ramipril	5.10 mg

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

Case No.	119 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	BIOXERA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00279633AM22
RA File Number	03AA040131282 AM22
Licence No and Date	0311009297/08/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **5/82-ALC4/2020 dated 09.10.2020** against advance authorization No. **3410045821 dt. 28.01.2020**, it was decided to ratify norms under Para 4.07 of HBP 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	1 kg	1	THIAMINE HYDROCHLORIDE	0.922 kg

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

Case No.	120 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00279782AM22
RA File Number	09AA04011868 AM22
Licence No and Date	0911001516/08/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Jan/202021/4 dated 12.02.2021** against advance authorization No. **0910068227 dt. 27.11.2019**, it was decided to ratify 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	Heparin Sodium Injection USP, 1000 USP Heparin Units/ml 10ml fill in a Vial(Each ml contains Heparin Sodium USP 1000 USP Heparin Units (From Porcine intestines), Benzyl alcohol NF 0.01ml, Water for Injection USP q.s.)	1 Number	1	Heparin Sodium	175.00 mg / vial
			2	Rubber Stoppers	Relevant as per packing policy
			3	Flip off Seals	Relevant as per packing policy
2	Heparin Sodium Injection USP, 1000 USP Heparin Units/ml 30ml fill in a Vial(Each ml contains Heparin Sodium USP 1000 USP Heparin Units (From Porcine intestines), Benzyl alcohol NF 0.01ml, Water for Injection USP q.s.)	1 Number	1	Heparin Sodium	291.67 mg / vial
			2	Rubber Stoppers	Relevant as per packing policy
			3	Flip off Seals	Relevant as per packing policy
3	Heparin Sodium Injection USP,	1 Number	1	Heparin Sodium	116.67 mg / vial

	5000 USP Heparin Units/ml 1ml fill in a Vial(Each ml contains Heparin Sodium USP 5000 USP Heparin Units (From Porcine intestines), Benzyl alcohol NF 0.01ml, Water for Injection USP q.s.)				
			2	Rubber Stoppers	Relevant as per packing policy
			3	Flip off Seals	Relevant as per packing policy

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

Case No.	121 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00279887AM22
RA File Number	09AA04018537 AM22
Licence No and Date	0911002024/08/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	122 / NC/3/MEET/Apr/202223/1				
Case Status	Case Approved				
Party Name	AARTI INDUSTRIES LTD				
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022				
HQ File Number	HQRNORM APPLY 00280152AM22				
RA File Number	03AA040121801 AM22				
Licence No and Date	0311009305/09/12/2021				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					

BENZENE		2	SODIUM HYPOPHOSPHITE	0.23 kg
		3	BROMINE	0.4945 kg
		4	HYDROGEN PEROXIDE 50%	0.1978 kg

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

Case No.	123 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00280232AM22
RA File Number	03AX04000052 AM22
Licence No and Date	0311009315/09/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Dec/202122/12 dated 17/12/2021** against advance authorization No. **0310839621 dt. 19.11.2020**, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
CLOPIDOGREL 75MG TABLETS Clopidogrel Zentiva / Clopidogrel Almus / Trombex(Each Tablet contain 75mg of CLOPIDOGREL BISULFATE FORM II	1 Number	1	CLOPIDOGREL BISULFATE FORM II	Net content in Export Description + 2%

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

Case No.	124 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022

Date				
HQ File Number	HQRNORM APPLY 00280354AM22			
RA File Number	03AA040128979 AM22			
Licence No and Date	0311009325/09/12/2021			
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Dec/202122/12 dated 17/12/2021 against advance authorization No. 0311005383 dt. 14-07-2021, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
CHLORAMPHENICOL EYE DROPS 10 ML((EACH VIAL CONTAINS CHLORAMPHENICOL MICRONISED 0.050GM NET WT OF BULK DRUG IS 18.98 KGS))	1 Number	1	Chloramphenicol Micronized	51.00 mg / Vial
RA concerned may take further necessary action as per above decision of NC.				

Case No.	125 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00280355AM22
RA File Number	03AA040124200 AM22
Licence No and Date	0311009326/09/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name. ii. Details of Packaging Material may be furnished. iii. Copy of Master Batch Formula for all export items indicating net content of inputs in each export.	

Case No.	126 / NC/3/MEET/Apr/202223/1
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Case Status	Case Approved																
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022																
HQ File Number	HQRNORM APPLY 00280583AM22																
RA File Number	31AX04000004 AM22																
Licence No and Date	3111000770/09/12/2021																
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Dec/202122/12 dated 17/12/2021 against advance authorization No. 3111000493 dt. 30-07-2021, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: <table border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> <tr> <td rowspan="3">DNOVO BP818 (Powder) (Tetra Methyl Bisphenol F)</td><td rowspan="3">1 kg</td><td>1</td><td>2,6 xylenol</td><td>1.06 kg</td></tr> <tr> <td>2</td><td>Paraformaldehyde</td><td>0.130 kg</td></tr> <tr> <td>3</td><td>Methanol</td><td>0.100 kg</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import items	Qty.	DNOVO BP818 (Powder) (Tetra Methyl Bisphenol F)	1 kg	1	2,6 xylenol	1.06 kg	2	Paraformaldehyde	0.130 kg	3	Methanol	0.100 kg
Export Product	Qty.	Sl. No.	Import items	Qty.													
DNOVO BP818 (Powder) (Tetra Methyl Bisphenol F)	1 kg	1	2,6 xylenol	1.06 kg													
		2	Paraformaldehyde	0.130 kg													
		3	Methanol	0.100 kg													

Case No.	127 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00281830AM22
RA File Number	05AX04000037 AM22
Licence No and Date	0511006792/10/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Oct/202122/10 dated 12/11/2021 against advance authorization No. 0511000310 dt. 21-12-2020, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Export product	Qty.	Sl. No.	Import items	Qty.
Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)-5ml(Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)-5ml)	1 Vial	1	Brinzolamide	51.00 mg / Vial

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

Case No.	128 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00281870AM22
RA File Number	05AX04000039 AM22
Licence No and Date	0511006799/10/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	129 / NC/3/MEET/Apr/202223/1			
Case Status	Case Approved			
Party Name	GLOBAL CALCIUM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022			
HQ File Number	HQRNORM APPLY 00283723AM22			
RA File Number	07AA04040800 AM22			
Licence No and Date	0711002618/13/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 12/82-ALC4/2018 dated 12.12.2018 against advance authorization No. 0710112292 dt. 23.10.2017 , it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

TIEMONIUM METHYLSULPHATE	1 kg	1	2-ACETYL THIOPHENE	0.75 kg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	130 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00283764AM22
RA File Number	09AA04017426 AM22
Licence No and Date	0911001978/13/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	131 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00283775AM22
RA File Number	07AA04040754 AM22
Licence No and Date	0711002620/13/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	132 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00283847AM22
RA File Number	03AX04000077 AM22
Licence No and Date	0311009414/13/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	133 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00283891AM22
RA File Number	09AA04018526 AM22
Licence No and Date	0911002040/13/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	134 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00283899AM22
RA File Number	09AX04000002 AM22
Licence No and Date	0911002041/13/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	135 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00283907AM22
RA File Number	09AX04000009 AM22
Licence No and Date	0911002042/13/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	136 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00283711AM22
RA File Number	07AA04040751 AM22

Licence No and Date	0711002615/13/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	137 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00284396AM22
RA File Number	05AX04000058 AM22
Licence No and Date	0511006831/13/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	138 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00285202AM22
RA File Number	09AA04017427 AM22
Licence No and Date	0911002053/14/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	139 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	COMBITIC GLOBAL CAPLET PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00286156AM22
RA File Number	33AA04008791 AM22
Licence No and Date	3311000515/15/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Jun/202122/2 dated 02/07/2021 against advance authorization No. 3311000189 dt. 19-04-2021, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the	

firm, whichever is less:

Export Product	Qty.	Sl. No.	Import items	Qty.
CIPROFLOXACIN TABLETS IP 500MG	1 Number	1	CIPROFLOXACIN HYDROCHLORIDE IP	555 mg / Tablet

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

Case No.	140 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	GRAMEN BOTANICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00286824AM22
RA File Number	05AA040108712 AM22
Licence No and Date	0511006918/15/12/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
BERBERINE HYDROCHLORIDE (97 PERCENT)	1 kg	1	BERBERIS ARISTATA EXTRACT	0.90 kg

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

Case No.	141 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	SHIVAM ADDITIVES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00286968AM22

RA File Number	13AX04000009 AM22			
Licence No and Date	1311000821/15/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Jun/202122/2 dated 02/07/2021 against advance authorization No. 1311000341 dt. 19-05-2021 , it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

Case No.	142 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00286998AM22
RA File Number	31AX04000006 AM22
Licence No and Date	3111000788/15/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	143 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	KUSUMA PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00287868AM22
RA File Number	03AX04000216 AM22
Licence No and Date	0311009541/16/12/2021
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	144 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00288115AM22
RA File Number	03AA040125782 AM22
Licence No and Date	0311009329/16/12/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import items	Qty.
Rosuvastatin Calcium USP / BP / EP	1 kg	1	Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate	1.30 kg

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

Case No.	145 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00288118AM22
RA File Number	03AA040128662 AM22
Licence No and Date	0311009547/16/12/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import items	Qty.
Rosuvastatin Calcium USP / BP / EP	1 kg	1	Tert-butyl 2-((4R,6S)-6-((E)-2-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethylsulfonamido)pyrimidin-5-yl)vinyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate	1.30 kg

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

Case No.	146 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00287478AM22
RA File Number	03AA040122138 AM22
Licence No and Date	0311009510/16/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	147 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00287541AM22
RA File Number	03AA040131415 AM22
Licence No and Date	0311009528/16/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	148 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022

HQ File Number	HQRNORM APPLY 00287549AM22
RA File Number	03AA040130524 AM22
Licence No and Date	0311009529/16/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name. ii. Details of Packaging Material may be furnished. iii. Copy of Master Batch Formula for all export items indicating net content of inputs in each export.	

Case No.	149 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00288929AM22
RA File Number	03AA040131485 AM22
Licence No and Date	0311009599/17/12/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	150 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00288969AM22
RA File Number	05AX04000134 AM22
Licence No and Date	0511006992/17/12/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	151 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022

HQ File Number	HQRNORM APPLY 00289566AM22
RA File Number	34AX04000036 AM22
Licence No and Date	3411001553/17/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	152 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00289569AM22
RA File Number	34AX04000035 AM22
Licence No and Date	3411001554/17/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	153 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00291474AM22
RA File Number	08AX04000083 AM22
Licence No and Date	0811003487/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	154 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00291533AM22
RA File Number	34AX04000052 AM22
Licence No and Date	3411001560/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	155 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00291684AM22
RA File Number	05AX04000180 AM22
Licence No and Date	0511007032/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	156 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00291710AM22
RA File Number	09AA04018176 AM22
Licence No and Date	0911002105/20/12/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
[(2R,5S)-5-(4-Amino-5-fluoro-2-oxo-2h-pyrimidin-1-yl)-[1,3]-oxathiolane-2-carboxylic acid, 2s-isopropyl-5r-methyl-1r- [(2R,5S)-5-(4-Amino-5-fluoro-2-oxo-2h-pyrimidin-1-yl)-[1,3]oxathiolane-2-carboxylic acid, s-isopropyl-5r-methyl-1r- cyclohexyl ester)] (FCE))	1 kg	1	GLYOXALIC ACID 50PCT	0.62 kg
		2	2 5 DIHYDROXY 1 4 DIATHINE	0.28 kg
		3	5 FLUOROCYTOSINE	0.44 kg
		4	DI METHYL FORMAMIDE	0.26 kg
		5	CYTOSINE	Not shown in the process or reaction

		6	HEXA METHYL DISILAZANE	0.29 kg
		7	METHYLENE DI CHLORIDE	2.63 kg
		8	L MENTHOL FRESH RECOVERY	0.61 kg
		9	TRI ETHYL AMINE	0.034 kg
		10	TRIPHOSGINE	0.40 kg

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

Case No.	157 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SUMAR BIOTECH LLP
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00291905AM22
RA File Number	08AX04000034 AM22
Licence No and Date	0811003488/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	158 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	MELZER CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00291926AM22
RA File Number	31AA04030064 AM22
Licence No and Date	3111000802/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	159 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022													
HQ File Number	HQRNORM APPLY 00291937AM22													
RA File Number	07AX04000071 AM22													
Licence No and Date	0711002685/20/12/2021													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to ratify 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>Sodium Chloride Injection USP 90mg per 10mL Vial.(10mL Vial - filled with 90mg of Sodium Chloride as bulk drug filled in 10mL Vial and capped with 13mm Grey Serum Chlorobutyl Rubber Stopper)</td> <td>1 Number</td> <td>1</td> <td>10ml Unprinted Clear Glass Vial Empty</td> <td>Relevant as per packing policy</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import items	Qty.	Sodium Chloride Injection USP 90mg per 10mL Vial.(10mL Vial - filled with 90mg of Sodium Chloride as bulk drug filled in 10mL Vial and capped with 13mm Grey Serum Chlorobutyl Rubber Stopper)	1 Number	1	10ml Unprinted Clear Glass Vial Empty	Relevant as per packing policy
Export Product	Qty.	Sl. No.	Import items	Qty.										
Sodium Chloride Injection USP 90mg per 10mL Vial.(10mL Vial - filled with 90mg of Sodium Chloride as bulk drug filled in 10mL Vial and capped with 13mm Grey Serum Chlorobutyl Rubber Stopper)	1 Number	1	10ml Unprinted Clear Glass Vial Empty	Relevant as per packing policy										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	160 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	INFICHEM PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00291201AM22
RA File Number	52AX04000002 AM22
Licence No and Date	5211001739/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	161 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00291953AM22

RA File Number	05AX04000176 AM22
Licence No and Date	0511007040/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	162 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00292375AM22
RA File Number	03AA040131528 AM22
Licence No and Date	0311009652/21/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	163 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00293146AM22
RA File Number	34AX04000029 AM22
Licence No and Date	3411001569/21/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	164 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00292389AM22
RA File Number	03AA040123994 AM22
Licence No and Date	0311009655/21/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	

- i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name.
- ii. Details of Packaging Material may be furnished.
- iii. Copy of Master Batch Formula for all export items indicating net content of inputs in each export.

Case No.	165 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00292436AM22
RA File Number	03AA040114422 AM22
Licence No and Date	0311009656/21/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	166 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00292437AM22
RA File Number	03AX04000252 AM22
Licence No and Date	0311009654/21/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name. ii. Details of Packaging Material may be furnished. iii. Copy of Master Batch Formula for all export items indicating net content of inputs in each export.	

Case No.	167 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SV PLASTOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00292805AM22

RA File Number	31AX04000016 AM22
Licence No and Date	3111000805/21/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and 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 alongwith stage wise percentage yields on molar basis. iii. Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis.	

Case No.	168 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00292962AM22
RA File Number	09AA04017854 AM22
Licence No and Date	0911002118/21/12/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	169 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	NATCO PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00293027AM22
RA File Number	09AX04000043 AM22
Licence No and Date	0911002121/21/12/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	170 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022

HQ File Number	HQRNORM APPLY 00293142AM22
RA File Number	05AX04000189 AM22
Licence No and Date	0511007079/21/12/2021
Norms Committee Decision:	
Deferred for comments of TE	

Case No.	171 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00293646AM22
RA File Number	03AX04000320 AM22
Licence No and Date	0311009690/22/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	172 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00293897AM22
RA File Number	31AX04000017 AM22
Licence No and Date	3111000824/22/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	173 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00293951AM22
RA File Number	34AX04000070 AM22
Licence No and Date	3411001584/22/12/2021
Norms Committee Decision:	
The Committee considered the request of firm for enhancement of norms and it was decided to call for following	

information / documents from the firm:

i. Quantity and Commercial Value of co-product Acetone obtained in manufacturing process.

Case No.	174 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00294320AM22
RA File Number	09AA04010826 AM22
Licence No and Date	0911002135/22/12/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import items	Qty.
Molnupiravir	1 kg	1	Cytidine	1.35 kg
		2	2,2-Dimethoxy propane	3.00 kg
		3	DBU (1, 8-diazabicyclo [5.4. 0] undec-7-ene	1.50 kg
		4	Isobutyric anhydride	0.90 kg
		5	Isopropyl alcohol	5.00 kg

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

Case No.	175 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00295585AM22

RA File Number	03AX04000358 AM22			
Licence No and Date	0311009732/23/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Jul/202122/4 dated 15/07/2021 against advance authorization No. 0311002953 dt. 30-03-2021, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
DOXYLEB CAPSULES (DOXYCYCLINE HYCLATE CAPSULES BP)100MG(IN PACKINGS OF 10X10s,10X100s & 1000s.QTY CONSUMED OF EXEMPT MATERIAL DOXYCYCLINE HYCLATE BP 117MG / CAPSULE.)	7905982 Number	1	DOXYCYCLINE HYCLATE BP	912.35 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	176 / NC/3/MEET/Apr/202223/1				
Case Status	Case Approved				
Party Name	RECKITT BENCKISER HEALTHCARE INDIA PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022				
HQ File Number	HQRNORM APPLY 00295676AM22				
RA File Number	05AX04000265 AM22				
Licence No and Date	0511007189/23/12/2021				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Jan/202122/13 dated 21/01/2022 against advance authorization No. 0510413971 dt. 13-04-2020, it was decided to ratify 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.
					(for 1 Number,

					100 ml Bottle)
1	Nurofen For Children Orange((Total qty in ML = 26,40,00,000 ML))	1 Number	1	Ibuprofen	2.10 gram
			2	Tween 80 (Polysorbate 80)	0.01 gram
			3	Glycerine	12.616 gram
			4	Lycasin 80/55 (Maltitol)	46.30 gram
			5	Sodium Saccharin 40/80	0.20 gram
			6	Citric Acid Monohydrate	0.40 gram
			7	Tri Sodium Citrate Dihydrate	0.509 gram
			8	Xanthan Gum	0.75 gram
			9	Sodium Chloride	0.11 gram
			10	Orange flavour	0.25 gram
			11	Domiphen Bromide (BP)	0.01 gram
			12	987 PP28mm M-LOC H&A White T/E	Relevant as per packing policy
			13	A001 5ML Syringe	
			14	0195 NRFN SYRNG PLG	
			15	Pet Bottle	

2	Nurofen For Children Strawberry((Total qty in ML = 3,60,00,000 ML))	1 Number	16	Ibuprofen	2.10 gram
			17	Tween 80 (Polysorbate 80)	0.01 gram
			18	Glycerine	12.616 gram
			19	Lycasin 80/55 (Maltotol)	46.30 gram
			20	Sodium Saccharin 40/80	0.20 gram
			21	Citric Acid Monohydrate	0.40 gram
			22	Tri Sodium Citrate Dihydrate	0.509 gram
			23	Xanthan Gum	0.75 gram
			24	Sodium Chloride	0.11 gram
			25	Straw flav KOSHER PHL-142134	0.25 gram
			26	Domiphen Bromide (BP)	0.01 gram
			27	987 PP28mm M-LOC H&A White T/E	Relevant as per packing policy
			28	A001 5ML Syrnge	
			29	0195 NRFN SYRNG PLG	
			30	Pet Bottle	

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

Case No.	177 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022

HQ File Number	HQRNORM APPLY 00295722AM22				
RA File Number	52AX04000016 AM22				
Licence No and Date	5211001759/23/12/2021				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Export product	Qty.	Sl. No.	Import items	Qty.	
1-(3-CHLORO PHENYL)4-(3-CHLORO PROPYL) PIPERAZINE HCL	1 kg	1	1,3-BROMO CHLORO PROPANE 99% min	0.924 kg	
RA concerned may take further necessary action as per above decision of NC.					

Case No.	178 / NC/3/MEET/Apr/202223/1				
Case Status	Case Approved				
Party Name	USV PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022				
HQ File Number	HQRNORM APPLY 00295371AM22				
RA File Number	03AX04000239 AM22				
Licence No and Date	0311009726/23/12/2021				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to ratify norms under Para 4.07 of HBP 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 Hyclate DR Tablets USP 100 mg , 100'S US((29,700 Bottles X 100 Per Bottles = 29,70,000 Tablets) (Total Weight of Export Product = 297.00 Kgs) (Net Content weight of Import Product = 351.83 kgs))	2970000 Tablets	1	Doxycyclin e Hyclate USP	342.74 kg	

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

Case No.	179 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00295564AM22
RA File Number	09AX04000038 AM22
Licence No and Date	0911002144/23/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	180 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00295569AM22
RA File Number	09AX04000039 AM22
Licence No and Date	0911002145/23/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	181 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00296310AM22
RA File Number	03AX04000251 AM22
Licence No and Date	0311009744/24/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name.	

- ii. **Details of Packaging Material may be furnished.**
 iii. **Copy of Master Batch Formula for all export items indicating net content of inputs in each export.**

Case No.	182 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00296314AM22
RA File Number	03AX04000229 AM22
Licence No and Date	0311009746/24/12/2021

Norms Committee Decision:

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

- i. **Description of all Excipients shown in items to be imported may be furnished as per their chemical name.**
 ii. **Details of Packaging Material may be furnished.**
 iii. **Copy of Master Batch Formula for all export items indicating net content of inputs in each export.**

Case No.	183 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	NEXUS PHARMA CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00296625AM22
RA File Number	08AX04000128 AM22
Licence No and Date	0811003535/24/12/2021

Norms Committee Decision:

Deferred for comments of TE.

Case No.	184 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	LARK LABORATORIES (INDIA) LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00296972AM22
RA File Number	05AX04000299 AM22
Licence No and Date	0511007234/24/12/2021

Norms Committee Decision:
Deferred for comments of TE.

Case No.	185 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00298292AM22
RA File Number	08AX04000091 AM22
Licence No and Date	0811003537/27/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	186 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00298304AM22
RA File Number	05AX04000086 AM22
Licence No and Date	0511007243/27/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	187 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00298421AM22
RA File Number	07AX04000126 AM22
Licence No and Date	0711002728/27/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Dec/202122/12 dated 17.12.2021 against advance authorization No. 0711001465 dt. 12.07.2021, it was decided to ratify norms under Para 4.07 of HBP 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.(10mL Vial - filled with 90mg of Sodium Chloride as bulk drug filled in 10mL Vial and capped with 13mm GreySerum ChlorobutyI Rubber Stopper)	1 Number	1	13mm Grey Serum ChlorobutyI R/S-RFS-C14226422GS6TP3	Relevant as per packing policy

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

Case No.	188 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	SAVLA CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00298647AM22
RA File Number	03AX04000385 AM22
Licence No and Date	0311009839/27/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	189 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	BIOXERA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00298677AM22
RA File Number	03AX04000380 AM22
Licence No and Date	0311009845/27/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 5/82-ALC4/2020 dated 09.10.2020 against advance authorization No. 3410045821 dt. 28.01.2020, it was decided to ratify norms under Para 4.07 of HBP 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	1 kg	1	THIAMINE HYDROCHLORIDE	0.922 kg

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

Case No.	190 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00298723AM22
RA File Number	09AX04000092 AM22
Licence No and Date	0911002161/27/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **03/AM21 dated 02/09/2020** against advance authorization No. **0910068027 dated 23.09.2019**, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
IBREXAFUNGERP CITRATE	1 kg	1	ENFUMAFUNGIN	4.55 kg

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

Case No.	191 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00298757AM22

RA File Number	09AX04000091 AM22			
Licence No and Date	0911002165/27/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 03/AM21 dated 02/09/2020 against advance authorization No. 0910068027 dated 23.09.2019, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
IBREXAFUNGERP CITRATE	1 kg	1	ENFUMAFUNGIN	4.55 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	192 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00298219AM22
RA File Number	03AX04000256 AM22
Licence No and Date	0311009818/27/12/2021
Norms Committee Decision:	
The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: Percentage API in the export product supported by DML.	

Case No.	193 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	VENOR PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00298924AM22
RA File Number	05AA04092052 AM22
Licence No and Date	0511007259/27/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Dec/202122/12 dated 17/12/2021** against advance authorization No. **6110001561 dated 28-11-2018**, it was decided to ratify 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	Inj. Fentanyl Citrate eqv. to Fentanyl 50 mcg/ml, 2 ml Ampoule(Finished formulation of Fentanyl Citrate)	3950070 Number	1	Fentanyl Citrate	682.18 gram
2	Inj. Fentanyl Citrate eqv. to Fentanyl 50 mcg/ml, 10 ml Ampoule(Finished formulation of Fentanyl Citrate)	289000 Number	1	Fentanyl Citrate	249.60 gram

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

Case No.	194 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00299344AM22
RA File Number	07AA04038998 AM22
Licence No and Date	0711002737/28/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	195 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	MAHARASHTRA ALDEHYDES AND CHEMICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00299560AM22
RA File Number	03AX04000272 AM22
Licence No and Date	0311009857/28/12/2021
Norms Committee Decision:	

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

- i. **Step wise manufacturing process.**
- ii. **Complete chemical reactions with molecular and structural formula and molecular weights alongwith stage wise percentage yields on molar basis.**
- iii. **Complete technical details as per Annexure to Appendix 4E for chemical products.**

Stoichiometric balance between import and export on molar basis.

Case No.	196 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	MAHARASHTRA ALDEHYDES AND CHEMICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00299562AM22
RA File Number	03AX04000273 AM22
Licence No and Date	0311009858/28/12/2021

Norms Committee Decision:

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

- i. **Step wise manufacturing process.**
- ii. **Complete chemical reactions with molecular and structural formula and molecular weights alongwith stage wise percentage yields on molar basis.**
- iii. **Complete technical details as per Annexure to Appendix 4E for chemical products.**

Stoichiometric balance between import and export on molar basis.

Case No.	197 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00299664AM22
RA File Number	09AX04000084 AM22
Licence No and Date	0911002182/28/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Mar/202122/15 dated 17/03/2022** against advance authorization No. **0911001083 dated 22-06-2021**, it was decided to ratify norms under Para 4.07 of HBP Vol. I as per details given below or as applied by

the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
4-chlorobutyryl chloride	1 kg	1	Gama butyrolactone	0.754 kg
		2	Thionyl Chloride	1.210 kg

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

Case No.	198 / NC/3/MEET/Apr/202223/1
Case Status	Case Approved
Party Name	AMI LIFESCIENCES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00299884AM22
RA File Number	34AX04000084 AM22
Licence No and Date	3411001595/28/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **5/82-ALC4/2020 dated 09.10.2020** against advance authorization No. **3410045821 dt. 28.01.2020**, it was decided to ratify norms under Para 4.07 of HBP 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	1 kg	1	THIAMINE HYDROCHLORIDE	0.922 kg

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

Case No.	199 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022

and Date	
HQ File Number	HQRNORM APPLY 00299896AM22
RA File Number	34AX04000090 AM22
Licence No and Date	3411001598/28/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	200 / NC/3/MEET/Apr/202223/1
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Apr/ 202223/ 1 and 29/04/2022
HQ File Number	HQRNORM APPLY 00299954AM22
RA File Number	09AX04000070 AM22
Licence No and Date	0911002189/28/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	