



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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(DES - III SECTION)**MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Dec/202223/17**DATED:** 13/01/2023Please Note

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

Meeting No. NC/3/MEET/Dec/202223/17 dated 13/01/2023 of Norms Committee - III for the year 2022-23 was held on 13/01/2023 under the Chairmanship of Rajiv Soni ,Joint DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2015-20.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	AJAY KUMAR,Deputy Director	DGFT(HQ)
2	NAND Lal,Technical Consultant	DPIIT
3	SHAISH KUMAR,Technical Consultant	DGFT
4	DINESHNARAIN MATHUR,Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00004919AM23
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee for explaining its case alongwith following documents / information: i. Approved Composition of Export Product / Label claim. ii. Master Batch formula for the export product. iii. COA of import item from foreign supplier. iv. Wastage claimed in each step of manufacturing process. v. Detailed calculation sheet for working out requirement. vi. Sample of Export Product and Import Item.	

Case No.	2 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00004920AM23
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee for explaining its case alongwith following documents / information: i. Approved Composition of Export Product / Label claim. ii. Master Batch formula for the export product. iii. COA of import item from foreign supplier. iv. Wastage claimed in each step of manufacturing process. v. Detailed calculation sheet for working out requirement. vi. Sample of Export Product and Import Item.	

Case No.	3 / NC/3/MEET/Dec/202223/17
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Case Status	Case Deferred
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00004921AM23
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: i. Approved Composition of Export Product / Label claim. ii. Master Batch formula for the export product. iii. COA of import item from foreign supplier. iv. Wastage claimed in each step of manufacturing process. v. Detailed calculation sheet for working out requirement. vi. Sample of Export Product and Import Item.	

Case No.	4 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	DELTA FINOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00235354AM22
RA File Number	039404000658 AM21
Licence No and Date	NA
Norms Committee Decision: The firm vide its reply furnished on portal has enclosed a copy of Advance Authorization No. 0311000410 dated 31.12.2020. It was observed that NC-3 in its Meeting No. NC/3/MEET/Jun/202223/5 dated 08/07/2022 has already rejected the case due to non-receipt of information from the firm. Hence, the Committee decided to reject the case with the instruction to the firm to file its representation on DGFT Portal under Review head. RA concerned may take further necessary action as per above decision of NC.	

Case No.	5 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	MYLAN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023

HQ File Number	HQRNORM REVIW00003162AM23
RA File Number	092404000288 AM13
Licence No and Date	0910053905/26/09/2012
Norms Committee Decision:	
The firm vide letter dated 07.11.2022 has furnished its reply on DGFT Portal. Deferred for comments of TE.	

Case No.	6 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	SHREE GANESH REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003812AM23
RA File Number	342404000295 AM15
Licence No and Date	3410040965/16/02/2015
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information / documents from the firm:	
Complete chemistry and material balance submitted at the time of obtaining Advance Authorization.	

Case No.	7 / NC/3/MEET/Dec/202223/17										
Case Status	Case Approved										
Party Name	TIDE INDUSTRIES										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023										
HQ File Number	HQRNORM REVIW00000196AM23										
RA File Number	342404000094 AM19										
Licence No and Date	3410044399/08/08/2018										
Norms Committee Decision:											
The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision of Norms Committee based on comments of Department of Chemical & Petrochemicals and Published Literature for production of Citronellol from Citral, it was decided to revise adhoc norms as under:											
<table><tr><td>Export Product</td><td>Qty</td><td>Sl. No.</td><td>Import Items</td><td>Qty</td></tr><tr><td>Rose Oxide (Tetrahydro-4-Methyl-2-(2-Methyl Propenyl) 2 H Pyran</td><td>1 kg</td><td>1</td><td>Citral Synthetic</td><td>4.17 kg</td></tr></table>		Export Product	Qty	Sl. No.	Import Items	Qty	Rose Oxide (Tetrahydro-4-Methyl-2-(2-Methyl Propenyl) 2 H Pyran	1 kg	1	Citral Synthetic	4.17 kg
Export Product	Qty	Sl. No.	Import Items	Qty							
Rose Oxide (Tetrahydro-4-Methyl-2-(2-Methyl Propenyl) 2 H Pyran	1 kg	1	Citral Synthetic	4.17 kg							

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

Case No.	8 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205000530AM20
RA File Number	522104000061 AM20
Licence No and Date	5210043148/14/08/2019
Norms Committee Decision: The Committee considered the case as per agenda and also the reply submitted by the firm and it was observed that the reply furnished by the firm is not clear. Hence, it was decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	9 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205000528AM20
RA File Number	522104000085 AM20
Licence No and Date	5210043146/14/08/2019
Norms Committee Decision: The Committee considered the case as per agenda and also the reply submitted by the firm and it was observed that the reply furnished by the firm is not clear. Hence, it was decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	10 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205000529AM20
RA File Number	522104000086 AM20
Licence No and Date	5210043147/14/08/2019
Norms Committee Decision:	

The Committee considered the case as per agenda and also the reply submitted by the firm and it was observed that the reply furnished by the firm is not clear. Hence, it was decided to **reject** the case.

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

Case No.	11 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00000392AM23
RA File Number	039404000496 AM20
Licence No and Date	0310831890/27/09/2019

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and it was observed that the Production / Consumption data furnished by the firm does not match with other manufacturers / exporters. 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.	12 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205000672AM20
RA File Number	039504000625 AM20
Licence No and Date	0310831873/27/09/2019

Norms Committee Decision:

Deferred for comments of TE.

Case No.	13 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00000393AM23
RA File Number	039404000497 AM20
Licence No and	0310831894/27/09/2019

Date	
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was observed that the Production / Consumption data furnished by the firm does not match with other manufacturers / exporters. 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.	14 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003549AM23
RA File Number	052404000377 AM20
Licence No and Date	0510412070/10/10/2019
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was observed that the firm has not provided any technical justification for enhancement. Hence, it was decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	15 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205000909AM20
RA File Number	522404000044 AM20
Licence No and Date	5210043258/12/12/2019
Norms Committee Decision: The Committee considered the case as per agenda and also the reply submitted by the firm and it was observed that the reply furnished by the firm is not clear. Hence, it was decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	16 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	AETHER INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205001130AM20
RA File Number	522404000068 AM20
Licence No and Date	5210043358/06/03/2020
Norms Committee Decision: The Committee considered the case as per agenda and also the reply submitted by the firm and it was observed that the reply furnished by the firm is not clear and also the export product name is too generic. Hence, it was decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	17 / NC/3/MEET/Dec/202223/17				
Case Status	Case Approved				
Party Name	S KANT HEALTHCARE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023				
HQ File Number	HQRNORM REVIW00003661AM23				
RA File Number	039504000715 AM20				
Licence No and Date	0310836133/07/05/2020				
Norms Committee Decision:					
The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	DI HYDRO ARTEMISININ	1 kg	1	ARTEMISININ	0.92 kg
2	ARTESUNATE	1 kg	2	ARTEMISININ	0.80 kg
3	ARTEMETHER	1 kg	3	ARTEMISININ	1.04 kg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	18 / NC/3/MEET/Dec/202223/17				
Case Status	Case Deferred				
Party Name	AMI ORGANICS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023				
HQ File Number	HQRNORM REVIW00003586AM23				

RA File Number	522404000007 AM21
Licence No and Date	5210043401/22/05/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	19 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	DELTA FINOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003546AM23
RA File Number	039404000112 AM21
Licence No and Date	0310836419/29/05/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	20 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205001363AM21
RA File Number	522404000004 AM21
Licence No and Date	5210043426/08/06/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and also the reply submitted by the firm and it was observed that the reply furnished by the firm is not clear and also the export product name is too generic. Hence, it was decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	21 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205001365AM21
RA File Number	522404000003 AM21
Licence No and Date	5210043427/09/06/2020
Norms Committee Decision:	

The Committee considered the case as per agenda and also the reply submitted by the firm and it was observed that the reply furnished by the firm is not clear and also the export product name is too generic. Hence, it was decided to **reject** the case.

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

Case No.	22 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205001386AM21
RA File Number	522404000017 AM21
Licence No and Date	5210043441/16/06/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and also the reply submitted by the firm and it was observed that the reply furnished by the firm is not clear. Hence, it was decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	23 / NC/3/MEET/Dec/202223/17
Case Status	Case Rejected
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205001405AM21
RA File Number	522404000016 AM21
Licence No and Date	5210043443/19/06/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and also the reply submitted by the firm and it was observed that the reply furnished by the firm is not clear and also the export product name is too generic. Hence, it was decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	24 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	BDR PHARMACEUTICALS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00002084AM23
RA File Number	039404000232 AM21

Licence No and Date	0310837216/15/07/2020				
Norms Committee Decision:					
The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	LEFLUNOMIDE 6.66% DCG (Each 100mg Granules contains:6.66 mg)(Net content of input/100gram=6.66gm,(66.60Gram/1kg),Total net content= 33.30kg)	500 kg	1	LEFLUNOMIDE	33.633 kg
2	LEFLUNOMIDE 13.33% DCG (Each 100mg Granules contains:13.33Gram)(Net content of input / 100gram = 13.33gm, (133.30Gram/1kg),Total net content=66.650kg)	500 kg	2	LEFLUNOMIDE	67.316 kg

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

Case No.	25 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	CONCORD BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205001614AM21
RA File Number	082404000395 AM20
Licence No and Date	0810148478/03/09/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	26 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205001756AM21
RA File Number	039404000825 AM20
Licence No and Date	0310838959/16/10/2020
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	27 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	EAST AFRICAN INDIA OVERSEAS
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	018205001829AM21
RA File Number	052304000263 AM21
Licence No and Date	0510415769/06/11/2020

Norms Committee Decision:

The Committee considered the case as per agenda and in the presence of the technical experts, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:

Export product	Qty.	Sl. No.	Import items	Qty.
NIPARIN 5ML (Heparin Sodium Injection 5000 Unit/ml)	25000 Numbers	1	Heparin Sodium IP 700 Mega Qty	687.5 MIU

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

Case No.	28 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ORIENTAL AROMATICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003798AM23
RA File Number	03AA04029725 AM21
Licence No and Date	0311002554/16/03/2021

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and it was observed that the reply furnished by the firm is not proper; hence it was decided to call the firm for attending **Personal Hearing** before Norms Committee for explaining its case.

Case No.	29 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	SAURAV CHEMICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM APPLY 00000680AM22			
RA File Number	30AA04006198 AM21			
Licence No and Date	3011000463/01/04/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and in the presence of the technical experts, it was decided to ratify the ad-hoc input output norms under para 4.7 of HBP as per details below or as applied by firm whichever is lower:				
Export product	Qty.	Sl. No.	Import items	Qty.
DEXKETOPROFEN TROMETAMOL	1 kg	1	3 1 CYANOETHYL BENZOIC ACID	1.06 kg
		2	N OCTYL D GLUCAMINE	0.36 kg
		3	TRIS AMINO BUFFER TROMETHAMINE	0.36 kg
RA may take appropriate action as per the decision of Norms Committee.				

Case No.	30 / NC/3/MEET/Dec/202223/17			
Case Status	Case Deferred			
Party Name	NEOGEN CHEMICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM REVIW00004030AM23			
RA File Number	03AA04033623 AM21			
Licence No and Date	0311003093/08/04/2021			
Norms Committee Decision:				
The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information / documents from the firm:				
i. Yield is just about 50%. Please submit any Publish Literature for low yield. ii. Production / Consumption data for last two years duly certified by GST. iii. Any earlier decision of Norms Committee for same export product.				

Case No.	31 / NC/3/MEET/Dec/202223/17			
Case Status	Case Deferred			

Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003538AM23
RA File Number	03AA04007907 AM22
Licence No and Date	0311003867/17/05/2021
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information / documents from the firm: i. Complete chemistry with Stoichiometric balance for increase in the quantity of Acetic Anhydrous. ii. Production / Consumption data for last two years duly certified by GST. iii. Any earlier such decision of Norms Committee for same export product.	

Case No.	32 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00104785AM22
RA File Number	039404000639 AM21
Licence No and Date	0311002735/01/06/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	33 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003753AM23
RA File Number	03AA04024304 AM22
Licence No and Date	0311004509/10/06/2021
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was observed that earlier the norms were fixed wrongly by taking one mole of Nonene. Now, the norms have been reworked taking two moles of Nonene, which is also used as a solvent. Hence, it was decided to revise adhoc norms as under:	

Export product	Qty.	Sl. No.	Import items	Qty.
DI-NONYLATED DIPHENYLAMINE (YALUB DND)	1 kg	1	DIPHENYLAMINE	0.4134 kg
		2	NONENE	0.800 kg
		3	ACTIVATED CLAY	0.05 kg

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

Case No.	34 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	LYRUS LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003920AM23
RA File Number	07AA04005177 AM22
Licence No and Date	0711001417/06/07/2021
Norms Committee Decision:	
The Committee considered the request of firm for fixation of adhoc norms and it was decided to call for following information / documents from the firm:	
i. DML. ii. Detailed calculation sheet to arrive at the import quantity.	

Case No.	35 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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 case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Export product	Qty.	Sl. No.	Import items	Qty.
Phenol	1 kg	1	Propylene	0.329 kg

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

Case No.	36 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003752AM23
RA File Number	03AA04045550 AM22
Licence No and Date	0311005604/25/07/2021

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and it was observed that earlier the norms were fixed wrongly by taking one mole of Nonene. Now, the norms have been reworked taking two moles of Nonene, which is also used as a solvent. Hence, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
DI-NONYLATED DIPHENYLAMINE (YALUB DND)	1 kg	1	DIPHENYLAMINE	0.4134 kg
		2	NONENE	0.800 kg
		3	ACTIVATED CLAY	0.05 kg

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

Case No.	37 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023

and Date	
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.	38 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00148419AM22
RA File Number	31AA04021097 AM22
Licence No and Date	3111000476/27/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Copy of DML with Approved Composition for each export product.	

Case No.	39 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00150128AM22
RA File Number	03AA04054005 AM22
Licence No and Date	0311005722/29/07/2021
Norms Committee Decision:	
The firm has furnished its reply. Deferred for comments of TE.	

Case No.	40 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	FINE ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00153334AM22
RA File Number	03AA04058605 AM22

Licence No and Date	0311005851/03/08/2021
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. Complete chemistry, molecular weight and percentage yield on molar basis as per Annexure to Appendix 4E.	

Case No.	41 / NC/3/MEET/Dec/202223/17										
Case Status	Case Approved										
Party Name	DEEPAK PHENOLICS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023										
HQ File Number	HQRNORM APPLY 00154532AM22										
RA File Number	342404000041 AM21										
Licence No and Date	3411000939/05/08/2021										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Phenol</td><td>1 kg</td><td>1</td><td>Propylene</td><td>0.329 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Phenol	1 kg	1	Propylene	0.329 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
Phenol	1 kg	1	Propylene	0.329 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	42 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	MEGHMANI NOVOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00160149AM22
RA File Number	08AA04019584 AM22
Licence No and Date	0811002298/11/08/2021

Norms Committee Decision:

The Committee considered the case as per agenda and it was observed that the reply furnished by the firm is not proper. Hence, it was decided to again call for following information / documents from the firm:

- i. **Production / Consumption data for last one year duly certified by GST.**
- ii. **Authentic Technical Literature or any Published Patent for the yield of 52.87% in this type of reaction.**

Case No.	43 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00161263AM22
RA File Number	52AA04010591 AM22
Licence No and Date	5211001166/12/08/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	44 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003533AM23
RA File Number	03AA04055267 AM22
Licence No and Date	0311006418/25/08/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	45 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	SV PLASTOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00176504AM22
RA File Number	31AA04025900 AM22
Licence No and Date	3111000564/03/09/2021
Norms Committee Decision:	

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

Export product	Qty.	Sl. No.	Import items	Qty.
MONO BUTYL TIN OXIDE (MBTO) (Not less than 98% purity)	1 kg	1	TIN INGOTS	0.496 kg
		2	TETRA BUTYL TIN TBT	0.487 kg

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

Case No.	46 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00177182AM22
RA File Number	05AA04076110 AM22
Licence No and Date	0511004515/06/09/2021

Norms Committee Decision:

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

- i. **Manufacturing process is not clear. Please give details of manufacturing process step wise indicating use of imported raw material namely Ethylene Dichloride & Fluorspar.**
- ii. **Stoichiometric balance to arrive at the quantity of raw material to produce 1 MT of Export Product.**

Case No.	47 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00177439AM22
RA File Number	09AA04011018 AM22
Licence No and Date	0911001497/06/09/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
HTHF(=S-(+)-3-HYDROXY TETRAHYDROFURAN)(SOLID)	1 kg	1	L MALIC ACID	2.54 kg

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

Case No.	48 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	DORF-KETAL CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00178330AM22
RA File Number	03AA04067379 AM22
Licence No and Date	0311006748/07/09/2021

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. **The value of By-Product formed in the reaction with evidence.**
- ii. **Calculation for the requirement of Heptanes – Solvent and its recovery.**

Case No.	49 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00178872AM22
RA File Number	34AA04007161 AM22
Licence No and Date	3411001079/07/09/2021

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. **Complete Chemistry giving chemical reaction with molecular weight and to indicate yield.**
 ii. **Material balance.**

Case No.	50 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00180144AM22
RA File Number	05AA04077131 AM22
Licence No and Date	0511004616/08/09/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to take inputs from the concerned Ministry and to call the firm for Personal Hearing before Norms Committee to explain their case.	

Case No.	51 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00180145AM22
RA File Number	05AA04077016 AM22
Licence No and Date	0511004617/08/09/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to take inputs from the concerned Ministry and to call the firm for Personal Hearing before Norms Committee to explain their case.	

Case No.	52 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00180146AM22
RA File Number	05AA04073979 AM22
Licence No and Date	0511004618/08/09/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to take inputs from the concerned Ministry and to call the firm for Personal Hearing before Norms Committee to explain their case.	

Case No.	53 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00181671AM22
RA File Number	34AA04006805 AM22
Licence No and Date	3411001099/10/09/2021
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. Complete Chemistry giving chemical reaction with molecular weight and to indicate yield. ii. Material balance.	

Case No.	54 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00183041AM22
RA File Number	03AA04090257 AM22
Licence No and Date	0311006909/13/09/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	55 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00183913AM22
RA File Number	05AA04078246 AM22
Licence No and Date	0511004729/14/09/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to take inputs from the concerned Ministry and to call the firm for Personal Hearing before Norms Committee to explain their case.	

Case No.	56 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	CUCKOS PHARMACEUTICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00184568AM22
RA File Number	33AA04006480 AM22
Licence No and Date	3311000430/15/09/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	57 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	GANGWAL CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00187865AM22
RA File Number	03AA04083531 AM22
Licence No and Date	0311007077/20/09/2021
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. Complete chemistry, molecular weight and percentage yield on molar basis as per Annexure to Appendix 4E. ii. Material Balance. iii. If mixing, then to give composition and calculation.	

Case No.	58 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ASOJ SOFT CAPS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00190578AM22
RA File Number	34AA04007816 AM22
Licence No and Date	3411001148/22/09/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	59 / NC/3/MEET/Dec/202223/17			
Case Status	Case Approved			
Party Name	CHEMPLAST SANMAR LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM APPLY 00190805AM22			
RA File Number	04AA04015436 AM22			
Licence No and Date	0411001511/22/09/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Phenyl Guanidine Carbonate	1 kg	1	Hydrogen Cyanamide 30 Percent	1.1 kg
		2	Aniline	0.626 kg
RA concerned may take further necessary action as per above decision of NC				

Case No.	60 / NC/3/MEET/Dec/202223/17			
Case Status	Case Deferred			
Party Name	INDO AMINES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM APPLY 00191007AM22			
RA File Number	03AA040103017 AM22			
Licence No and Date	0311007156/23/09/2021			
Norms Committee Decision:				
Deferred for comments of TE.				

Case No.	61 / NC/3/MEET/Dec/202223/17			
Case Status	Case Deferred			
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM APPLY 00192148AM22			

RA File Number	03AA04091496 AM22
Licence No and Date	0311007180/23/09/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	62 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00193597AM22
RA File Number	03AA04097753 AM22
Licence No and Date	0311007198/25/09/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	63 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	INDO AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00194032AM22
RA File Number	03AA04083866 AM22
Licence No and Date	0311007213/25/09/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	64 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00195617AM22
RA File Number	09AA04010498 AM22
Licence No and Date	0911001381/28/09/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/202223/7 dated 16/09/2022 against advance authorization No.	

0911000482 dated 24/05/2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export Product	Qty	Sl. No.	Import Items	Qty
1	Low molecular weight Heparin Enoxaparin Sodium Injection USP, 20mg in 0.2ml Pre filled Syringe(Composition per syringe, Enoxaparin Sodium USP 20mg, Water for Injection USP q.s. to 0.2ml)	500000 Numbers	1	Enoxaparin Sodium	22.00 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Plunger Stoppers	Net + 5% wastage
			4	Plunger Rods	Net + 2% wastage
			5	Preventis Needle Shielding System	Net + 2% wastage
2	Low molecular weight Heparin Enoxaparin Sodium Injection USP, 40mg in 0.4ml Pre filled Syringe(Composition per syringe, Enoxaparin Sodium USP 40mg, Water for Injection USP q.s. to 0.4ml)	4200000 Numbers	1	Enoxaparin Sodium	44.00 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Plunger Stoppers	Net + 5% wastage
			4	Plunger Rods	Net + 2% wastage
			5	Preventis Needle Shielding System	Net + 2% wastage
3	Low molecular weight Heparin Enoxaparin Sodium Injection USP 60mg in 0.6ml Pre filled Syringe(Composition per syringe, Enoxaparin Sodium USP 60mg, Water for Injection USP q.s. to 0.6ml)	800000 Numbers	1	Enoxaparin Sodium	66.00 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Plunger Stoppers	Net + 5% wastage
			4	Plunger Rods	Net + 2% wastage
			5	Preventis Needle Shielding System	Net + 2% wastage
4	Low molecular weight Heparin	356900	1	Enoxaparin Sodium	88.00 mg

	Enoxaparin Sodium Injection USP 80mg in 0.8ml Pre filled Syringe(Composition per syringe, Enoxaparin Sodium USP 80mg, Water for Injection USP q.s. to 0.8ml)	Numbers	2	Barrel Syringes	Net + 5% wastage
			3	Plunger Stoppers	Net + 5% wastage
			4	Plunger Rods	Net + 2% wastage
			5	Preventis Needle Shielding System	Net + 2% wastage

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

Case No.	65 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	NATURAL AND ESSENTIAL OILS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00196404AM22
RA File Number	07AA04026654 AM22
Licence No and Date	0711002016/28/09/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the reply furnished by the firm is not clear. Hence, it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case.	

Case No.	66 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	VACHICHEM INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003902AM23
RA File Number	07AA04028991 AM22
Licence No and Date	0711002024/30/09/2021
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information / documents from the firm:	
Production / Consumption data duly certified by GST.	

Case No.	67 / NC/3/MEET/Dec/202223/17
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Case Status	Case Approved
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00199265AM22
RA File Number	03AA040107419 AM22
Licence No and Date	0311007392/01/10/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/14 dated 07/12/2022** against advance authorization No. **0311005091 dated 04/07/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

(A)

Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	ALLOPURINOL TABLETS 100MG (Each Allopurinol Tablet of 100mg contains Allopurinol 100mg)(Equivalent to:-Cyano Acetamide 0.0001mg ,Triethyl Ortho formate 0.00021mg, Formamide 0.00015 mg, Morpholine 0.00013mg , Hydrazine Hydrate 0.00006 mg) (Cross SION Norms of Allopurinol SION No.A2321 & Tablets/Capsules SION NoA412))	1 Number	1	Allopurinol	102.00 mg / 100 mg Tablet
2	ALLOPURINOL TABLETS 300MG (Each Allopurinol Tablet of 300mg contains Allopurinol 300 mg)(Equivalent to:-Cyano Acetamide 0.0003mg ,Triethyl Ortho-formate 0.00063mg, Formamide 0.00045 mg, Morpholine 0.00039mg , Hydrazine Hydrate 0.00018 mg) (Cross SION Norms of Allopurinol SION No.A2321 & Tablets/Capsules SION NoA412.))	1 Number	2	Allopurinol	306.00 mg / 300 mg Tablet

(B)

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

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

Case No.	68 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	ARJUNA NATURAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00199626AM22
RA File Number	10AA04009843 AM22
Licence No and Date	1011000579/01/10/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
Caffeine Extract Powder 95%	3582 kg	1	Caffeine Powder Kraft paper bag 25 Kg N2VN	Relevant as per packing policy

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

Case No.	69 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00205042AM22
RA File Number	03AA040108575 AM22
Licence No and Date	0311007542/07/10/2021
Norms Committee Decision:	
The firm has furnished its reply on DGFT Portal. Deferred for comments of TE.	

Case No.	70 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	CHEMPLAST SANMAR LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00206478AM22
RA File Number	04AA04028427 AM22
Licence No and Date	0411001606/08/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	71 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00206565AM22
RA File Number	09AA04010507 AM22
Licence No and Date	0911001380/08/10/2021
Norms Committee Decision:	
Deferred for comments of TE	

Case No.	72 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred

Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00208798AM22
RA File Number	05AA04089568 AM22
Licence No and Date	0511005321/11/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	73 / NC/3/MEET/Dec/202223/17													
Case Status	Case Approved													
Party Name	DEEPAK PHENOLICS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023													
HQ File Number	HQRNORM APPLY 00210066AM22													
RA File Number	34AA04008458 AM22													
Licence No and Date	3411001256/12/10/2021													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Dec/202223/15 dated 29/12/2022 against advance authorization No. 3411002469 dated 30/06/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Phenol</td><td>1 MT</td><td>1</td><td>Cumene</td><td>0.84466 MT</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	Phenol	1 MT	1	Cumene	0.84466 MT
Export product	Qty.	Sl. No.	Import items	Qty.										
Phenol	1 MT	1	Cumene	0.84466 MT										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	74 / NC/3/MEET/Dec/202223/17			
Case Status	Case Deferred			
Party Name	NEON LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM APPLY 00210390AM22			
RA File Number	03AA040106734 AM22			
Licence No and Date	0311007655/12/10/2021			

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. **Copy of DML with Approved Composition.**
- ii. **Copy of Master Batch Formula.**
- iii. **COA of import item from foreign supplier.**

Case No.	75 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AMARA LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00211472AM22
RA File Number	09AA04016055 AM22
Licence No and Date	0911001711/13/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	76 / NC/3/MEET/Dec/202223/17			
Case Status	Case Approved			
Party Name	STERILE INDIA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM APPLY 00211729AM22			
RA File Number	05AA04088434 AM22			
Licence No and Date	0511005403/13/10/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Piperacillin and Tazobactam Sodium Sterile (8:1)	1 kg	1	PIPERACILLIN ACID	0.890 kg
		2	TAZOBACTAM ACID	0.1078 kg

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

Case No.	77 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00212058AM22
RA File Number	03AA040109332 AM22
Licence No and Date	0311007711/14/10/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing alongwith sample of Export Product and Import Items</u> before Norms Committee for explaining its case.	

Case No.	78 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003807AM23
RA File Number	03AA040110385 AM22
Licence No and Date	0311007732/17/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	79 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	LUPIN LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00215795AM22
RA File Number	03AA040109357 AM22
Licence No and Date	0311007760/18/10/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Complete chemistry, molecular weight and percentage yield on molar basis for API as per Annexure to	

Appendix 4E.

Case No.	80 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00220582AM22
RA File Number	05AA04091028 AM22
Licence No and Date	0511005555/21/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	81 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00220583AM22
RA File Number	05AA04091027 AM22
Licence No and Date	0511005556/21/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	82 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00220585AM22
RA File Number	05AA04090983 AM22
Licence No and Date	0511005557/21/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	83 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	BHAGWATI INDUSTRIES
Meeting Number	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023

and Date	
HQ File Number	HQRNORM APPLY 00219420AM22
RA File Number	08AA04033013 AM22
Licence No and Date	0811002934/21/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	84 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00220580AM22
RA File Number	05AA04091063 AM22
Licence No and Date	0511005553/21/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	85 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00221158AM22
RA File Number	07AA04035636 AM22
Licence No and Date	0711002187/22/10/2021
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 report of import and export item. ii. Manufacturing process indicating stage wise wastage of raw material. iii. Justification / reason for high wastage of raw material.	

Case No.	86 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023

HQ File Number	HQRNORM APPLY 00221196AM22			
RA File Number	07AA04035640 AM22			
Licence No and Date	0711002189/22/10/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Oct/202223/11 dated 31/10/2022 against advance authorization No. 0711002508 dated 02/12/2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
CALCIUM LACTATE GLUCONATE	1 kg	1	CALCIUM LACTATE PENTAHYDRATE	0.490 kg
		2	CALCIUM GLUCONATE	0.680 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	87 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	THEMIS NUTRITIONALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00221695AM22
RA File Number	03AA040108212 AM22
Licence No and Date	0311007847/22/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	88 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	OLON ACTIVE PHARMACEUTICAL INGREDIENTS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00222021AM22
RA File Number	03AA040112432 AM22
Licence No and Date	0311007856/22/10/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
Quetiapine Fumarate Micronised	1 kg	1	Dibenzo [b,f] [1,4] Thiazepine-11- [10H]-one Dibenzo-[b,f][1,4]-thiazepin-11(10H)-one (CAS 3159-07-7)	0.580 kg
		2	1-[2-(2-Hydroxyethoxy) Ethyl Piperazine 2-Hydroxy Ethyl Ethoxy Piperazine CAS 13349-82-1	0.714 kg

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

Case No.	89 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00226905AM22
RA File Number	05AA04094141 AM22
Licence No and Date	0511005704/26/10/2021
Norms Committee Decision:	
The application of firm was forwarded to Department of Biotechnology (DBT) on 05.01.2023. Comments awaited from DBT.	

Case No.	90 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00227461AM22
RA File Number	03AA04097792 AM22
Licence No and Date	0311007966/27/10/2021
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	91 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	KREATIVE ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00229743AM22
RA File Number	09AA04016534 AM22
Licence No and Date	0911001791/28/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	92 / NC/3/MEET/Dec/202223/17										
Case Status	Case Approved										
Party Name	STERILE INDIA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023										
HQ File Number	HQRNORM APPLY 00229799AM22										
RA File Number	05AA04094507 AM22										
Licence No and Date	0511005751/28/10/2021										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>CEFEPIME FOR INJECTION</td><td>1 kg</td><td>1</td><td>CEFEPIME HCL NON STERILE</td><td>0.6357 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	CEFEPIME FOR INJECTION	1 kg	1	CEFEPIME HCL NON STERILE	0.6357 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
CEFEPIME FOR INJECTION	1 kg	1	CEFEPIME HCL NON STERILE	0.6357 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	93 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00230750AM22

RA File Number	09AA04016788 AM22				
Licence No and Date	0911001796/29/10/2021				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Calcium and Colecalciferol Tablets 500mg/400 IU(D-CALSOR 500mg/400 IU)	1 Number	1	Colecalciferol concentrate (powder form)] (Dry Vitamin D3 100 SD/S)	4.08 mg
2	Calcium and Colecalciferol Tablets 500mg/800 IU(D-CALSOR 500mg/800 IU)	1 Number	2	Colecalciferol concentrate (powder form)] (Dry Vitamin D3 100 SD/S)	8.16 mg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	94 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	BHARAT PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00239596AM22
RA File Number	34AA04008748 AM22
Licence No and Date	3411001363/02/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	95 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003766AM23
RA File Number	03AA040116810 AM22
Licence No and Date	0311008170/02/11/2021
Norms Committee Decision:	

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

Stoichiometric balance on molecular weight basis and percentage yield to arrive at the quantity of raw material asked for.

Case No.	96 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00239722AM22
RA File Number	07AA04038456 AM22
Licence No and Date	0711002275/02/11/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Oct/202223/11 dated 31/10/2022** against advance authorization No. **0711002507 dated 02/12/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
ZINC GLUCONATE POWDER	1 kg	1	ZINC GLUCONATE GRANULAR	1.005 kg

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

Case No.	97 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AARTI INDUSTRIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00246187AM22
RA File Number	03AA04078980 AM22
Licence No and Date	0311008372/09/11/2021

Norms Committee Decision:

Deferred for comments of TE.

Case No.	98 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	LUPIN LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00246330AM22
RA File Number	03AA040117679 AM22
Licence No and Date	0311008378/09/11/2021
Norms Committee Decision: The firm has enclosed a copy of application submitted to RA, Mumbai for issuance of subject Advance Authorization under Para 4.18 of HBP Vol. I (Non-Infringing Process). Authorization issued under Para 4.18 does not require approval of NC. The Committee discussed the case and it was decided to verify from RA, Mumbai whether the Advance Authorization was issued to firm on Para 4.18. If yes, then RA, Mumbai may also clarified, why the application was forwarded to NC-3, when the Advance Authorization was issued to firm on the basis of Para 4.18 of HBP Vol. I	

Case No.	99 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	NITIKA PHARMACEUTICAL SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00245623AM22
RA File Number	50AA04003867 AM22
Licence No and Date	5011000294/09/11/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	100 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	FREESIA CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00249915AM22
RA File Number	03AA040117893 AM22
Licence No and Date	0311008508/12/11/2021
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. **Complete chemistry, molecular weight and percentage yield on molar basis as per Annexure to Appendix 4E.**
- ii. **Justification for low yield.**

Case No.	101 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00253243AM22
RA File Number	34AA04009242 AM22
Licence No and Date	3411001396/15/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	102 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00253270AM22
RA File Number	05AA04099135 AM22
Licence No and Date	0511006147/15/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	103 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00255683AM22
RA File Number	09AA04016606 AM22
Licence No and Date	0911001869/17/11/2021
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	104 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00255868AM22
RA File Number	03AA040112749 AM22
Licence No and Date	0311008637/17/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	105 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	HELLA INFRA MARKET PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00255252AM22
RA File Number	03AA040117899 AM22
Licence No and Date	0311008615/17/11/2021
Norms Committee Decision:	
Deferred for comments of TE	

Case No.	106 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	HELLA INFRA MARKET PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00255254AM22
RA File Number	03AA040120188 AM22
Licence No and Date	0311008616/17/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	107 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023

and Date	
HQ File Number	HQRNORM APPLY 00255297AM22
RA File Number	34AA04009240 AM22
Licence No and Date	3411001409/17/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	108 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	SARACA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00256800AM22
RA File Number	09AA04017459 AM22
Licence No and Date	0911001876/18/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	109 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ARKRAY HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00257390AM22
RA File Number	52AA04018127 AM22
Licence No and Date	5211001587/18/11/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Department of Biotechnology (DBT).	

Case No.	110 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00261092AM22
RA File Number	09AA04016734 AM22
Licence No and Date	0911001888/22/11/2021
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. **Molecular weight of export product.**
- ii. **Justification for low yield.**
- iii. **Minutes of previous approved Minutes for the same export product / import item**

Case No.	111 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00262423AM22
RA File Number	05AA04098088 AM22
Licence No and Date	0511006367/23/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	112 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00262432AM22
RA File Number	05AA04098038 AM22
Licence No and Date	0511006369/23/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	113 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00262564AM22
RA File Number	03AA04013560 AM22
Licence No and Date	0311008775/23/11/2021
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 along with stage wise percentage yields on molar basis.**
- iii. **Complete technical details as per Annexure to Appendix 4E for chemical products.**
- iv. **Stoichiometric balance between import and export on molar basis.**
- v. **Details of indigenous input with quantity.**

Case No.	114 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	LAZERHEAD LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00266328AM22
RA File Number	09AA04012424 AM22
Licence No and Date	0911001950/26/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	115 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00268778AM22
RA File Number	09AA04017927 AM22
Licence No and Date	0911001956/29/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	116 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00272089AM22
RA File Number	07AA04039105 AM22
Licence No and	0711002509/02/12/2021

Date	
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 report of import and export item. ii. Manufacturing process indicating stage wise wastage of raw material. iii. Justification / reason for high wastage of raw material.	

Case No.	117 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00272098AM22
RA File Number	07AA04040797 AM22
Licence No and Date	0711002517/02/12/2021
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. Complete chemistry, molecular weight, percentage yield on molar basis etc. as per Annexure to Appendix 4E. ii. COA of import item from foreign supplier.	

Case No.	118 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00272724AM22
RA File Number	03AA040127775 AM22
Licence No and Date	0311009114/02/12/2021
Norms Committee Decision: The firm was asked to submit certain information on DGFT Portal. However, the firm has intimated that its Technical Manager is out of station and it will submit reply after he returns from leave. The Committee considered the request of firm and it was decided to defer the case.	

Case No.	119 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	RAKSHIT PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	120 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	121 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	122 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AURA PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	123 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00279887AM22
RA File Number	09AA04018537 AM22
Licence No and Date	0911002024/08/12/2021

Norms Committee Decision:

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

Sl. No.	Export Product	Qty	Sl. No.	Import Items	Qty
1	Esmolol Hydrochloride in Sodium Chloride Injection 2000 mg per 100ml (20mg per ml) single dose bags(Each ml Contains: Esmolol Hydrochloride USP 10mg, Sodium Chloride USP 5.9mg, Water for Injection USP q.s., Sodium Acetate Trihydrate USP 2.8mg, Glacial Acetic Acid USP 0.546mg, Sodium Hydroxide and or Hydrochloric Acid q.s. to adjust Ph)	1 Number	1	Esmolol Hydrochloride	2100 mg
			2	Flexible bags	1.02 Numbers
			3	Twist off port stoppers	1.01 Numbers
2	Esmolol Hydrochloride in Sodium Chloride Injection 2500 mg per 250ml (10mg per ml) single dose bags(Each ml Contains: Esmolol Hydrochloride USP 10mg, Sodium Chloride USP 5.9mg, Water for Injection USP q.s., Sodium Acetate Trihydrate USP 2.8mg, Glacial Acetic Acid USP 0.546mg, Sodium Hydroxide and or Hydrochloric Acid q.s. to adjust Ph)	1 Number	1	Esmolol Hydrochloride	2625 mg
			2	Flexible bags	1.02 Numbers
			3	Twist off port stoppers	1.01 Numbers

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

Case No.	124 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00283711AM22
RA File Number	07AA04040751 AM22
Licence No and Date	0711002615/13/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Oct/202223/11 dated 31/10/2022** against advance authorization No. **0710109429 dated 23/02/2016**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	EXPORT PRODUCT	QTY.	Sl. No.	IMPORT ITEMS	QTY.
1	MAGNESIUM CITRATE (USP/ NONAHYDRATE Eur.Ph/ ANHYDROUS Eur.Ph/ DODECAHYDRATE Eur.Ph)	1 kg	1	CITRIC ACID	1.001 kg
			2	MAGNESIUM CARBONATE	0.730 kg
2	CALCIUM CITRATE(USP)	1 kg	1	CITRIC ACID	0.816 kg
			2	CALCIUM CARBONATE	0.660 kg
3	ZINC CITRATE (USP)	1 kg	1	CITRIC ACID	0.880 kg
4	POTASSIUM CITRATE (BP/Eur.Ph/ USP)	1 kg	1	CITRIC ACID	0.859 kg

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

Case No.	125 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	126 / NC/3/MEET/Dec/202223/17																						
Case Status	Case Approved																						
Party Name	GLAND PHARMA LIMITED																						
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023																						
HQ File Number	HQRNORM APPLY 00283891AM22																						
RA File Number	09AA04018526 AM22																						
Licence No and Date	0911002040/13/12/2021																						
Norms Committee Decision:																							
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:																							
<table><tr><th>Export Product</th><th>Qty</th><th>Sl. No.</th><th>Import Items</th><th>Qty</th></tr><tr><td rowspan="5">Ganirelix Acetate Injection, 250mcg/0.5ml fill in 1ml PFS(Each Prefilled Syringe contains: Ganirelix Acetate 250mcg, Glacial Acetic acid USP 0.1mg, Mannitol USP 23.5mg, Water for Injection USP q.s. to 0.5ml, Acetic acid USP q.s. to adjust the PH, Sodium Hydroxide USP NF q.s. to adjust the PH)</td><td rowspan="5">1 Number</td><td>1</td><td>Ganirelix Acetate</td><td>275 mcg</td></tr><tr><td>2</td><td>Barrel Syringes</td><td>1.05 Numbers</td></tr><tr><td>3</td><td>Plunger Stoppers</td><td>1.05 Numbers</td></tr><tr><td>4</td><td>Plunger Rods</td><td>1.02 Numbers</td></tr><tr><td>5</td><td>Preventis Needle Shielding System</td><td>1.02 Numbers</td></tr></table>		Export Product	Qty	Sl. No.	Import Items	Qty	Ganirelix Acetate Injection, 250mcg/0.5ml fill in 1ml PFS(Each Prefilled Syringe contains: Ganirelix Acetate 250mcg, Glacial Acetic acid USP 0.1mg, Mannitol USP 23.5mg, Water for Injection USP q.s. to 0.5ml, Acetic acid USP q.s. to adjust the PH, Sodium Hydroxide USP NF q.s. to adjust the PH)	1 Number	1	Ganirelix Acetate	275 mcg	2	Barrel Syringes	1.05 Numbers	3	Plunger Stoppers	1.05 Numbers	4	Plunger Rods	1.02 Numbers	5	Preventis Needle Shielding System	1.02 Numbers
Export Product	Qty	Sl. No.	Import Items	Qty																			
Ganirelix Acetate Injection, 250mcg/0.5ml fill in 1ml PFS(Each Prefilled Syringe contains: Ganirelix Acetate 250mcg, Glacial Acetic acid USP 0.1mg, Mannitol USP 23.5mg, Water for Injection USP q.s. to 0.5ml, Acetic acid USP q.s. to adjust the PH, Sodium Hydroxide USP NF q.s. to adjust the PH)	1 Number	1	Ganirelix Acetate	275 mcg																			
		2	Barrel Syringes	1.05 Numbers																			
		3	Plunger Stoppers	1.05 Numbers																			
		4	Plunger Rods	1.02 Numbers																			
		5	Preventis Needle Shielding System	1.02 Numbers																			
RA concerned may take further necessary action as per above decision of NC																							

Case No.	127 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00283899AM22
RA File Number	09AX04000002 AM22
Licence No and Date	0911002041/13/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202223/15 dated 29/12/2022** against advance authorization No. **0910066874 dated 20/11/2018**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export Product	Qty.	Sl. No.	Import Items	Qty.
AMOXYCILLIN AND CLAVULANATE POTASSIUM TABLETS 1000 MG(Each tablet contains amoxicillin 875 mg and potassium clavulanate equivalent to clavulanic acid 125 mg) The relevant bulk drug content in the export product is Amoxycillin Trihydrate is 12687.5Kgs and Clavulanate Potassium is 1812.5Kgs))	14500 Numbers	1	6-Amino penicillanic acid (6-APA)	7350.63 kg
		2	D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]	6232.51 kg
		3	Penicillin G Amidase	28.47 kg
		4	Diluted Clavulanate Potassium (1:1) / Potassium Clavulanate Diluted with Microcrystalline Cellulose (1:1)	3697.50 kg

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

Case No.	128 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	129 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	130 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	131 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	132 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	INFICHEM PHARMA PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	133 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00291684AM22
RA File Number	05AX04000180 AM22
Licence No and Date	0511007032/20/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to take inputs from the concerned Ministry and to call the firm for Personal Hearing before Norms Committee to explain their case.	

Case No.	134 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	SUMAR BIOTECH LLP
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	135 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00291953AM22
RA File Number	05AX04000176 AM22
Licence No and Date	0511007040/20/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to take inputs from the concerned Ministry and to call the firm for **Personal Hearing** before Norms Committee to explain their case.

Case No.	136 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	137 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00292962AM22
RA File Number	09AA04017854 AM22
Licence No and Date	0911002118/21/12/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
sodium (S)-4-oxo-4,6,7,8-tetrahydropyrrolo [1,2-a]pyrimidine-6-carboxylate((Pyrimidinone acid, sodium salt))	1 kg	1	Methyl L-pyroglutamate	2.70 kg
		2	Triethyl amine	2.27 kg
		3	2,5-Norbornadiene	1.73 kg
		4	Chloro sulfonyl isocyanate	2.778 kg

		5	Isopropyl alcohol	4.02 kg
		6	Methyl tert butyl ether	5.91 kg
		7	Toluene	5.72 Litre
		8	Ethyl acetate	2.95 Litre
		9	N-Heptane	1.82 kg
		10	Ethyl benzene	1.00 kg
		11	Methanol	1.50 kg
		12	Methylene chloride	3.25 Litre

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

Case No.	138 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	NATCO PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00293027AM22
RA File Number	09AX04000043 AM22
Licence No and Date	0911002121/21/12/2021

Norms Committee Decision:

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	NITROGLYCERIN SUBLINGUAL TABLETS USP 0.3 mg Each Tablet contains Nitroglycerin USP 0.3 mg (2x1,80,000=3,60,000 Tablets)	1 Number	1	DILUTED NITROGLYCERIN USP 1.95 percent	15.70 mg
			2	Glyceryl Monostearate (Imwitor 491 powder)	1.255 mg

2	NITROGLYCERIN SUBLINGUAL TABLETS USP 0.4mg Each Tablet contains Nitroglycerin USP 0.4 mg (4x12,00,000=48,00,000 Tablets)	1 Number	3	DILUTED NITROGLYCERIN USP 1.95 percent	20.93 mg
			4	Glyceryl Monosterate (Imwitor 491 powder)	1.255 mg
3	NITROGLYCERIN SUBLINGUAL TABLETS USP 0.6 mg Each Tablet contains Nitroglycerin USP 0.6 mg (2x1,80,000=3,60,000 Tablets)	1 Number	5	DILUTED NITROGLYCERIN USP 1.95 percent	31.40 mg
			6	Glyceryl Monosterate (Imwitor 491 powder)	1.255 mg

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

Case No.	139 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	140 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	141 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	LARK LABORATORIES (INDIA) LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
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.	142 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00299344AM22
RA File Number	07AA04038998 AM22
Licence No and Date	0711002737/28/12/2021
Norms Committee Decision:	
The firm has furnished its reply on DGFT Portal. Deferred for comments of TE.	

Case No.	143 / NC/3/MEET/Dec/202223/17				
Case Status	Case Approved				
Party Name	AUROBINDO PHARMA LTD				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023				
HQ File Number	HQRNORM APPLY 00299954AM22				
RA File Number	09AX04000070 AM22				
Licence No and Date	0911002189/28/12/2021				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Calcium and Colecalciferol Tablets 500mg/400 IU(D-CALSOR 500mg/400 IU)	1 Number	1	Colecalciferol concentrate (powder form)] (Dry Vitamin D3 100 SD/S)	4.08 mg

2	Calcium and Colecalciferol Tablets 500mg/800 IU(D-CALSOR 500mg/800 IU)	1 Number	2	Colecalciferol concentrate (powder form)] (Dry Vitamin D3 100 SD/S)	8.16 mg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	144 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM REVIW00003747AM23
RA File Number	03AX04000607 AM22
Licence No and Date	0311010239/07/01/2022

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and it was observed that earlier the norms were fixed wrongly by taking one mole of Nonene. Now, the norms have been reworked taking two moles of Nonene, which is also used as a solvent. Hence, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
DI-NONYLATED DIPHENYLAMINE (YALUB DND)	1 kg	1	DIPHENYLAMINE	0.4134 kg
		2	NONENE	0.800 kg
		3	ACTIVATED CLAY	0.05 kg

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

Case No.	145 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	MEGHMANI NOVOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00357589AM22
RA File Number	08AX04000262 AM22

Licence No and Date	0811004084/16/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. End use of Export Product. ii. Justification for low yield of 52.87% with any Published Literature. iii. Percentage recovery of Methanol. iv. Commercial Value of Zinc Chloride Anhydrous obtained as a By-Product. v. Production / Consumption data for 2022 duly certified by GST.	

Case No.	146 / NC/3/MEET/Dec/202223/17			
Case Status	Case Approved			
Party Name	YASHO INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM REVIW00003846AM23			
RA File Number	03AX04001322 AM22			
Licence No and Date	0311011513/17/02/2022			
Norms Committee Decision:				
The Committee considered the request of firm for review of adhoc norms and it was observed that earlier the norms were fixed wrongly by taking one mole of Nonene. Now, the norms have been reworked taking two moles of Nonene, which is also used as a solvent. Hence, it was decided to revise adhoc norms as under:				

Case No.	147 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	KUBO COMBUSTION EFFICIENCY CHEMICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM APPLY 00359704AM22			
RA File Number	03AX04001024 AM22			
Licence No and Date	0311011564/18/02/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
PROPIOPHENONE(Apperance : Colourless to Pale yellow clear liquid, Purity by GC : 99% Min. Moisture : 0.5% Max)	1 kg	1	Propionic Acid	0.7077 kg
		2	Benzoic Acid	1.1820 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	148 / NC/3/MEET/Dec/202223/17			
Case Status	Case Approved			
Party Name	TIDE INDUSTRIES			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM APPLY 00359641AM22			
RA File Number	34AX04000278 AM22			
Licence No and Date	3411001821/18/02/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Oct/202223/11 dated 31/10/2022 against advance authorization No. 3411000694 dated 04/06/2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Gamma- Decalactone	100000 kg	1	Acrylic Acid	83843.00 kg
		2	Di tert Butyl Peroxide	31000.00 kg

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

Case No.	149 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00364287AM22
RA File Number	05AX04001048 AM22
Licence No and Date	0511010134/23/02/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to take inputs from the concerned Ministry and to call the firm for Personal Hearing before Norms Committee to explain their case.	

Case No.	150 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	MEGHMANI FINECHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00364297AM22
RA File Number	34AX04000289 AM22
Licence No and Date	3411001842/23/02/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Step wise manufacturing process. ii. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. iii. Complete technical details as per Annexure to Appendix 4E for chemical products. iv. Stoichiometric balance between import and export on molar basis v. Details of indigenous input with quantity.	

Case No.	151 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	KusuMa PharMa
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00365147AM22

RA File Number	03AX04001369 AM22
Licence No and Date	0311011710/23/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Process of manufacturing in detail. ii. COA of import item and export product indicating difference in specification of import and export.	

Case No.	152 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00366482AM22
RA File Number	05AX04001055 AM22
Licence No and Date	0511010494/24/02/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	153 / NC/3/MEET/Dec/202223/17			
Case Status	Case Approved			
Party Name	YASHO INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM REVIW00003847AM23			
RA File Number	03AX04001474 AM22			
Licence No and Date	0311011969/28/02/2022			
Norms Committee Decision:				
The Committee considered the request of firm for review of adhoc norms and it was observed that earlier the norms were fixed wrongly by taking one mole of Nonene. Now, the norms have been reworked taking two moles of Nonene, which is also used as a solvent. Hence, it was decided to revise adhoc norms as under:				
</				

(YALUB DND)		2	NONENE	0.800 kg
		3	ACTIVATED CLAY	0.05 kg

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

Case No.	154 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AASHA BIOCHEM
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00370268AM22
RA File Number	10AX04000065 AM22
Licence No and Date	1011000912/28/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	155 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ARENE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00371807AM22
RA File Number	09AX04000256 AM22
Licence No and Date	0911002585/01/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	156 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00371439AM22
RA File Number	09AA04017878 AM22
Licence No and Date	0911002574/01/03/2022
Norms Committee Decision:	

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

Export product	Qty.	Sl. No.	Import items	Qty.
Amoxicillin Tablets 875mg((Each Tablet contains, Amoxicillin equivalent to Anhydrous Amoxicillin 875mg))	1 Number	1	6-Amino Penicillanic Acid (6-APA)	581.77 mg
		2	Methyl d-(-)-4-hydroxy-phenylglycinate OR D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester]	510.17 mg
		3	Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)	2.25 mg

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

Case No.	157 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00371441AM22
RA File Number	09AX04000232 AM22
Licence No and Date	0911002575/01/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	158 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	AROHEMA INGREDIENTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00374231AM22
RA File Number	26AX04000019 AM22
Licence No and Date	2611000488/03/03/2022
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	159 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	SRIAM LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00374328AM22
RA File Number	09AX04000286 AM22
Licence No and Date	0911002611/03/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	160 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	MISTAIR HEALTH AND HYGIENE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00375016AM22
RA File Number	03AX04001352 AM22
Licence No and Date	0311012252/04/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	161 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	VIVIMED LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00378088AM22
RA File Number	04AX04000278 AM22
Licence No and Date	0411002806/07/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	162 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023

and Date	
HQ File Number	HQRNORM APPLY 00378736AM22
RA File Number	03AX04001550 AM22
Licence No and Date	0311012347/07/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	163 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00378768AM22
RA File Number	05AX04001194 AM22
Licence No and Date	0511010747/07/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	164 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	RA CHEM PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002388AM23
RA File Number	09AX04000378 AM23
Licence No and Date	0911003424/01/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	165 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002393AM23
RA File Number	03AX04002517 AM23
Licence No and Date	0311016775/01/08/2022
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	166 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002410AM23
RA File Number	31AX04000136 AM23
Licence No and Date	3111001598/02/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	167 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002411AM23
RA File Number	03AX04002508 AM23
Licence No and Date	0311016795/02/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	168 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	INDO AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002415AM23
RA File Number	03AX04002490 AM23
Licence No and Date	0311016801/02/08/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. 12/AM18 dated 04.05.2018 against advance authorization No. 0310790966 dated 12.11.2014, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Export product	Qty.	Sl. No.	Import items	Qty.
SORBITAN MONO OLEATE OR IAL SMO	1 kg	1	Sorbitol 70 %	0.425 kg

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

Case No.	169 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	S.V.CHEM INTERMEDIATES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002400AM23
RA File Number	04AX04000404 AM23
Licence No and Date	0411003747/02/08/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity.	

Case No.	170 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002401AM23
RA File Number	09AX04000379 AM23
Licence No and Date	0911003427/02/08/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	171 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred

Party Name	APTRA SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002435AM23
RA File Number	09AX04000268 AM23
Licence No and Date	0911003430/03/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	172 / NC/3/MEET/Dec/202223/17			
Case Status	Case Approved			
Party Name	BALAJI AMINES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM APPLY 00002437AM23			
RA File Number	31AX04000125 AM23			
Licence No and Date	3111001605/03/08/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Nov/202223/14 dated 07/12/2022 against advance authorization No. 3111000158 dated 08/03/2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
MORPHOLINE (ORGANIC CHEMICAL)	1 kg	1	DIETHYLENE GLYCOL	1.279 kg
		2	AMMONIA ANHYDROUS	0.217 kg
		3	HYDROGEN	Not allowed, as it is procured indigenously.
		4	MORPHOLINE CATALYST	Not allowed as no catalogue is available.

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

Case No.	173 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	NIFTY LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002449AM23
RA File Number	09AX04000391 AM23
Licence No and Date	0911003436/03/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	174 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002451AM23
RA File Number	31AX04000133 AM23
Licence No and Date	3111001608/03/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	175 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ASSOCIATED DYESTUFF PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002465AM23
RA File Number	08AX04000717 AM23
Licence No and Date	0811005686/04/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	176 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023

and Date	
HQ File Number	HQRNORM APPLY 00002474AM23
RA File Number	34AX04000434 AM23
Licence No and Date	3411002610/04/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	177 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002477AM23
RA File Number	09AX04000348 AM23
Licence No and Date	0911003442/04/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	178 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	METROPOLITAN EXIMCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002481AM23
RA File Number	03AX04002332 AM23
Licence No and Date	0311016872/04/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	179 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002458AM23
RA File Number	07AX04000654 AM23
Licence No and Date	0711004840/04/08/2022
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
Sodium Bicarbonate Injection 84mg/mL - 50mL Vial(Sodium Bicarbonate as bulk drug filled in 50mL Vial and capped with 20mm Bromobutyl Grey Rubber Stopper)	109059 Numbers	1	50 mL / 20mm neck Serum Type I CLR, Molded Vials	Relevant as per packing policy

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

Case No.	180 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002486AM23
RA File Number	07AX04000657 AM23
Licence No and Date	0711004850/05/08/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Oct/202223/11 dated 31/10/2022** against advance authorization No. **0711002512 dated 02/12/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	CALCIUM LACTOBIONATE	1 kg	1	LACTOSE	0.3635 kg
			2	CALCIUM CARBONATE	0.052795 kg
2	CALCIUM BROMO	1 kg	1	LACTOSE	1.021 kg

	LACTOBIONATE		2	CALCIUM CARBONATE	0.360 kg
			3	HYDROBROMIC ACID	0.510 kg
3	CALCIUM GLUBIONATE	1 kg	1	LACTOSE	0.829 kg
			2	CALCIUM CARBONATE	0.140 kg
			3	CALCIUM GLUCONATE	0.42 kg
4	LACTOBIONIC ACID	1 kg	1	LACTOSE	0.5071 kg
			2	CALCIUM CARBONATE	0.0738 kg

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

Case No.	181 / NC/3/MEET/Dec/202223/17
Case Status	Case Approved
Party Name	ENALTEC LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002495AM23
RA File Number	03AX04002527 AM23
Licence No and Date	0311016905/05/08/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **7/82-ALC4/2020 dated 04/12/2020** against advance authorization No. **0310837576 dated 10/08/2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Febuxostat	1 kg	1	2-[3-Cyano-4-(2-Methylpropoxy) Phenyl]-4-Methyl-5-Thiazolecarboxylic Acid Ethyl Ester	1.25 kg

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

Case No.	182 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002501AM23
RA File Number	03AX04002642 AM23
Licence No and Date	0311016913/05/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	183 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002513AM23
RA File Number	03AX04002600 AM23
Licence No and Date	0311017010/08/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	184 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002517AM23
RA File Number	03AX04002627 AM23
Licence No and Date	0311017022/08/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	185 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred

Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002518AM23
RA File Number	07AX04000655 AM23
Licence No and Date	0711004861/08/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	186 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	PRACHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002520AM23
RA File Number	08AX04000754 AM23
Licence No and Date	0811005702/08/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	187 / NC/3/MEET/Dec/202223/17			
Case Status	Case Approved			
Party Name	DEEPAK PHENOLICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023			
HQ File Number	HQRNORM APPLY 00002521AM23			
RA File Number	34AX04000427 AM23			
Licence No and Date	3411002623/08/08/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Dec/202223/15 dated 29/12/2022 against advance authorization No. 3411002553 dated 19/07/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

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

Case No.	188 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002528AM23
RA File Number	08AX04000709 AM23
Licence No and Date	0811005708/08/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	189 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002532AM23
RA File Number	34AX04000447 AM23
Licence No and Date	3411002627/08/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	190 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002512AM23
RA File Number	03AX04002601 AM23
Licence No and Date	0311017009/08/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	191 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred

Party Name	INDO AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002547AM23
RA File Number	03AX04002507 AM23
Licence No and Date	0311017047/10/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	192 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002548AM23
RA File Number	03AX04002511 AM23
Licence No and Date	0311017048/10/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	193 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	ALCHEMIE FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002553AM23
RA File Number	03AX04002069 AM23
Licence No and Date	0311017059/10/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	194 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002560AM23
RA File Number	34AX04000414 AM23
Licence No and Date	3411002630/10/08/2022

Norms Committee Decision:
Deferred for comments of TE.

Case No.	195 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002566AM23
RA File Number	30AX04000206 AM23
Licence No and Date	3011002481/10/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	196 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002571AM23
RA File Number	03AX04002399 AM23
Licence No and Date	0311017082/10/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	197 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002572AM23
RA File Number	03AX04002688 AM23
Licence No and Date	0311017083/10/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	198 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002546AM23
RA File Number	03AX04002602 AM23
Licence No and Date	0311017046/10/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	199 / NC/3/MEET/Dec/202223/17
Case Status	Case Deferred
Party Name	RAKSHIT PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023
HQ File Number	HQRNORM APPLY 00002581AM23
RA File Number	09AX04000400 AM23
Licence No and Date	0911003458/10/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	200 / NC/3/MEET/Dec/202223/17															
Case Status	Case Approved															
Party Name	PIRAMAL PHARMA LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202223/ 17 and 13/01/2023															
HQ File Number	HQRNORM APPLY 00002590AM23															
RA File Number	03AX04002681 AM23															
Licence No and Date	0311017097/11/08/2022															
Norms Committee Decision:																
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Nov/202223/12 dated 18.11.2022 against advance authorization No. 0311013250 dated 23.03.2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:																
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Bempedoic Acid and Ezetimibe Fixed Dose Combination Tablets (Each Tablet content</td><td>1 Number</td><td>1</td><td>Bempedoic Acid</td><td>189.90 mg</td></tr><tr><td>Bempedoic Acid 180mg and Ezetimibe</td><td></td><td></td><td></td><td></td></tr></table>		Export Product	Qty.	Sl. No.	Import items	Qty.	Bempedoic Acid and Ezetimibe Fixed Dose Combination Tablets (Each Tablet content	1 Number	1	Bempedoic Acid	189.90 mg	Bempedoic Acid 180mg and Ezetimibe				
Export Product	Qty.	Sl. No.	Import items	Qty.												
Bempedoic Acid and Ezetimibe Fixed Dose Combination Tablets (Each Tablet content	1 Number	1	Bempedoic Acid	189.90 mg												
Bempedoic Acid 180mg and Ezetimibe																

10mg((Net content of Bempedoic Acid 2700 kgs and Ezetimibe 150 kgs in total Export Qty) (AA for Free of cost material as per Para 4.11 of HBP & Para 4.19 of FTP & RBI Master Circular C-26 - Disallowing remittances for material being supplied free of cost))		2	Ezetimibe	10.55 mg
Note: The above norms are valid only for subject to fulfillment of following conditions: 1. Export Product being Patented Medicine, be filed with USFDA as an NDA (New Drug Application. 2. Export to USA and Europe only. 3. Firm holding Certificate of Manufacturing Exclusivity.				
RA concerned may take further necessary action as per above decision of NC.				