



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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

(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Dec/202324/17

DATED: 20/12/2023

Please Note

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

Meeting No. NC/3/MEET/Dec/202324/17 dated 20/12/2023 of Norms Committee - III for the year 2023-24 was held on 20/12/2023 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	UTTAM SARKAR,Assistant Section Officer	DGFT(HQ)
2	Raman Kumar,Deputy DGFT	DGFT(HQ)
3	NAND Lal,Technical Consultant	DPIIT
4	SHAISH KUMAR,Technical Consultant	DGFT
5	DINESHNARAIN MATHUR,Technical Consultant	DGFT
6	Nand Lal,Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00004206AM24
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 to explain its case alongwith following information / documents from the firm :- i. Molar Weight of each input and output item of each stage. ii. Percentage yield on molar basis for each step. iii. CA certified Production/Consumption data. iv. Sample of Shipping Bills and Bill of Entry of the export products along with statement of Input-output as per export documents of the said authorization.	

Case No.	2 / NC/3/MEET/Dec/202324/17
Case Status	Case Rejected
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00004197AM24
RA File Number	092404000413 AM12
Licence No and Date	0910050238/15/12/2011
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm had neither attended the Personal Hearing nor intimated to committee. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	3 / NC/3/MEET/Dec/202324/17
Case Status	Case Rejected
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00003005AM24
RA File Number	092404000287 AM14
Licence No and	0910057785/01/10/2013

Date	
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm had neither attended the Personal Hearing nor intimated to committee. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	4 / NC/3/MEET/Dec/202324/17
Case Status	Case Rejected
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00003009AM24
RA File Number	092404000044 AM15
Licence No and Date	0910059969/01/05/2014
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm had neither attended the Personal Hearing nor intimated to committee. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	5 / NC/3/MEET/Dec/202324/17
Case Status	Case Rejected
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00003004AM24
RA File Number	092404000421 AM15
Licence No and Date	0910061287/21/11/2014
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm had neither attended the Personal Hearing nor intimated to committee. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	6 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	CLARION ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005834AM24
RA File Number	502404000002 AM16
Licence No and Date	5010002211/29/06/2015

Norms Committee Decision:

Shri Vivek Tiwari, Director, and Shri Gyanesh Jadoa, Production (Head) of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty	S.No.	Import Item	Qty. allowed
3-Hydroxy Acetophenone (99% Assy. Value)	1 Kg.	1	Acetophenone (99.50% Assy. Value)	2.04 kg

Note: The above norms are for regularization and closure purpose only.

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

Case No.	7 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006372AM24
RA File Number	039504000304 AM17
Licence No and Date	0310806238/14/07/2016

Norms Committee Decision:

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

Export Product	Qty	S.No.	Import Item	Qty. allowed
D Alpha Tocopherol having Net content of Fatty Acid Distillate/Deoderised Distillate 727000.00 kgs. Methenol 99 Percent	1 Kg.	1	Fatty Acid Distillate Deoderised Distillate	30.00 kg
		2	Methenol 99%	9.18 kg

222400.00 kg. S Heptane 71200.00 kg. Acetone 29000.00 kg.		3	S-Heptane	2.94 kg
		4	Acetone	1.20 kg

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

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

Case No.	8 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000261AM24
RA File Number	039404000617 AM17
Licence No and Date	0310808312/06/10/2016
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	9 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	CLARION ORGANICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM REVIW00005838AM24			
RA File Number	502404000013 AM17			
Licence No and Date	5010002312/16/12/2016			
Norms Committee Decision:				
Shri Vivek Tiwari, Director, and Shri Gyanesh Jadoa, Production (Head) of the firm had attended the Personal Hearing and explained firm’s case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is lower: -				
Export Product	Qty	S.No.	Import Item	Qty. allowed

3-Hydroxy Acetophenone (99% Assy. Value)	1 Kg.	1	Acetophenone (99.50% Assy. Value)	2.04 kg
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Note: The above norms are for regularization and closure purpose only.

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

Case No.	10 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000263AM24
RA File Number	039404001181 AM17
Licence No and Date	0310812323/03/04/2017
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	11 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006373AM24
RA File Number	039504000999 AM17
Licence No and Date	0310812435/11/04/2017
Norms Committee Decision:	
Shri Kunal Sikchi, Director and Shri Nitin Vyas, Sr. Executive of the firm had attended the Personal Hearing and explained firm’s case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less:-	

content of Fatty Acid Distillate/Deoderised Distillate 727000.00 kgs. Methenol 99 Percent 222400.00 kg. S Heptane 71200.00 kg. Acetone 29000.00 kg.			Distillate	
		2	Methenol 99%	9.18 kg
		3	S-Heptane	2.94 kg
		4	Acetone	1.20 kg

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

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

Case No.	12 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006374AM24
RA File Number	039504000267 AM18
Licence No and Date	0310814547/11/07/2017

Norms Committee Decision:

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

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

		4	Acetone	1.20 kg
Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms. RA concerned may take further necessary action as per above decision of NC.				

Case No.	13 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000262AM24
RA File Number	039404000295 AM18
Licence No and Date	0310814908/31/07/2017
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	14 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006375AM24
RA File Number	039504000651 AM18
Licence No and Date	0310817413/29/11/2017
Norms Committee Decision:	
Shri Kunal Sikchi, Director and Shri Nitin Vyas,Sr. Executive of the firm had attended the Personal Hearing and explained firm’s case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less:-	

Distillate/Deoderised Distillate 727000.00 kgs. Methenol 99 Percent 222400.00 kg. S Heptane 71200.00 kg. Acetone 29000.00 kg.		2	Methenol 99%	9.18 kg
		3	S-Heptane	2.94 kg
		4	Acetone	1.20 kg

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

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

Case No.	15 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000265AM24
RA File Number	039404000822 AM18
Licence No and Date	0310818765/30/01/2018
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	16 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006289AM24
RA File Number	039404000911 AM18
Licence No and Date	0310819230/19/02/2018
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	17 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023

and Date	
HQ File Number	HQRNORM REVIW00006376AM24
RA File Number	039504000037 AM19
Licence No and Date	0310820676/26/04/2018

Norms Committee Decision:

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

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

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

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

Case No.	18 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006968AM23
RA File Number	039404000258 AM19
Licence No and Date	0310821966/27/06/2018

Norms Committee Decision:

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

Case No.	19 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006377AM24
RA File Number	039504000488 AM19
Licence No and Date	0310824019/26/09/2018

Norms Committee Decision:

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

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

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

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

Case No.	20 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000260AM24
RA File Number	039404000753 AM19

Licence No and Date	0310825758/18/12/2018
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	21 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000752AM24
RA File Number	052404000438 AM19
Licence No and Date	0510410372/25/04/2019
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	22 / NC/3/MEET/Dec/202324/17																			
Case Status	Case Approved																			
Party Name	ASCENT FINECHEM PRIVATE LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023																			
HQ File Number	HQRNORM REVIW00000818AM24																			
RA File Number	082404000026 AM20																			
Licence No and Date	0810145127/30/04/2019																			
Norms Committee Decision:																				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under.																				
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="3">N-(3-AMINOPROPYL) IMIDAZOLE WHITE OR OFF WHITE CRYSTAL</td><td rowspan="3">1 kg.</td><td>1</td><td>Imidazole</td><td>0.712 kg.</td></tr><tr><td>2</td><td>SODIUM METHOXIDE POWDER</td><td>1.00 kg.</td></tr><tr><td>3</td><td>ACRYLONITRILE</td><td>0.500 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	N-(3-AMINOPROPYL) IMIDAZOLE WHITE OR OFF WHITE CRYSTAL	1 kg.	1	Imidazole	0.712 kg.	2	SODIUM METHOXIDE POWDER	1.00 kg.	3	ACRYLONITRILE	0.500 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
N-(3-AMINOPROPYL) IMIDAZOLE WHITE OR OFF WHITE CRYSTAL	1 kg.	1	Imidazole	0.712 kg.																
		2	SODIUM METHOXIDE POWDER	1.00 kg.																
		3	ACRYLONITRILE	0.500 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	23 / NC/3/MEET/Dec/202324/17																											
Case Status	Case Approved																											
Party Name	INDO AMINES LIMITED																											
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023																											
HQ File Number	HQRNORM REVIW00005846AM24																											
RA File Number	039404000179 AM20																											
Licence No and Date	0310829884/25/06/2019																											
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:- <table border="1"> <thead> <tr> <th>S.No</th><th>Export Product</th><th>Qty</th><th>S.No.</th><th>Import Item</th><th>Qty. allowed</th></tr> </thead> <tbody> <tr> <td rowspan="2">1</td><td rowspan="3">Tallow Amine (IAL TA)</td><td rowspan="3">1 Kg</td><td>1</td><td>C 16 18 Fatty Acid</td><td>1.57 kg</td></tr> <tr> <td>2</td><td>Ni Catalyst</td><td>0.001 kg</td></tr> <tr> <td colspan="6">OR</td></tr> <tr> <td>2</td><td>Stearyl Amines 100 (IAL SA 100)</td><td>1Kg</td><td>1</td><td>C 16 18 Fatty Acid</td><td>1.80 kg</td></tr> </tbody> </table>		S.No	Export Product	Qty	S.No.	Import Item	Qty. allowed	1	Tallow Amine (IAL TA)	1 Kg	1	C 16 18 Fatty Acid	1.57 kg	2	Ni Catalyst	0.001 kg	OR						2	Stearyl Amines 100 (IAL SA 100)	1Kg	1	C 16 18 Fatty Acid	1.80 kg
S.No	Export Product	Qty	S.No.	Import Item	Qty. allowed																							
1	Tallow Amine (IAL TA)	1 Kg	1	C 16 18 Fatty Acid	1.57 kg																							
			2	Ni Catalyst	0.001 kg																							
OR																												
2	Stearyl Amines 100 (IAL SA 100)	1Kg	1	C 16 18 Fatty Acid	1.80 kg																							
RA concerned may take further necessary action as per above decision of NC.																												

Case No.	24 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	CONCORD BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001262AM24
RA File Number	082404000101 AM20
Licence No and Date	0810145581/27/06/2019
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevent information / documents.	

Case No.	25 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	AETHER INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM REVIW00005919AM24			
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 it was decided to fix adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty	Sl. No.	Import Item	Qty. allowed
3-METHOXY-2-METHYLLLENZOYL CHLORIDE.	1 Kg	1	2,6-DICHLOROTOLUENE	1.90 kg
		2	TETRAHYDROFURAN	1.50 kg
		3	DIMETHYLSULFOXIDE	1.37 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	26 / NC/3/MEET/Dec/202324/17		
Case Status	Case Approved		
Party Name	ENCUBE ETHICALS PRIVATE LIMITED		
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023		
HQ File Number	HQRNORM REVIW00004761AM23		
RA File Number	039404000395 AM20		
Licence No and Date	0310831546/13/09/2019		
Norms Committee Decision:			
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms for export to US only are as under:-			
S.No	Export Product	Quantity	
1	SECURA PROTECTIVE CREAM 2.75 Oz 78 Gms Tube	1 Number	
2	SECURA PROTECTIVE CREAM 40 GM TUBES	1 Number	

3	SECURA PROTECTIVE CREAM 1.75 OZ 50 Gms TUBE	1 Number
4	SECURA PROTECTIVE OINTMENT 2.47 Oz 70 GM TUBE	1 Number
5	SECURA PROTECTIVE OINTMENT 5.6 Oz 159 GM TUBE	1 Number
6	SECURA MOISTURIZING CREAM 3 Oz 85 GM TUBE	1 Number
7	SECURA MOSITURIZING CREAM 6.5 Oz 184 GM Tube	1 Number
8	SECURA EXTRA PROTECTIVE CREAM 3.25 Oz 92 GMS TUBE	1 Number
9	SECURA EXTRA PROTECTIVE CREAM 7.75 Oz 219.70 GM TUBE	1 Number
10	SECURA ANTIFUNGAL EXTRA THICK PROTECTIVE CREAM 92 GMS TUBE	1 Number
11	UNICARE MOISTURIZING LOTION 8 Oz 236 ML	1 Number
12	UNICARE MOISTURIZING LOTION 2 Oz 60 ML	1 Number
13	UNI DERM MOISTURIZING CREAM 3 Oz 85 Gms Tube	1 Number
14	UNI DERM MOISTURIZING CREAM 80 GMS TUBE	1 Number
15	SECURA EXTRA PROTECTIVE CREAM 90 GMS TUBE	1 Number
16	SECURA ANTI FUNGAL GREASELESS 2 Oz 57 GM TUBE	1 Number
17	SOLOSITE WOUND GEL 3 Oz 85 Gm TUBE	1 Number
18	SOLOSITE WOUND GEL 20 GM TUBE	1 Number
19	SOLOSITE SOOTHING, HYDRATING, HEALING GEL 50 GM TUBE	1 Number
20	SECURA MOISTURIZING LOTION 8 Oz 236 ML	1 Number
21	SECURA MOISTURIZING LOTION 60 ML	1 Number

22	SOLOSITE SOOTHING,HYDRATING HEALING GEL 20 GM TUBE	1 Number
23	SOLOSITE SOOTHING,HYDRATING HEALING GEL 100 GM TUBE	1 Number

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

Note:

1. 0.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**
2. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**
3. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption

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

Case No.	27 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006304AM24
RA File Number	082404000202 AM20
Licence No and Date	0810146231/25/09/2019
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jan/202223/18 dated 23.01.2023** against advance authorization No. **0811006083 dated 22.09.2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: -

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop((Considering the loss on drying @14.50% of Bulkdrug for 300MG we need to poor 350.88 Mg. So net content of the raw material is :- 72000 Bottles * 5 ML * 350.88 MG = 126.32 Kgs.))	72000.0 Numbers	1	Metamizole Magnesium	114.923 Kg
2	Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop((Considering the loss on drying @14.50% of Bulkdrug for 300MG we need to poor 350.88 Mg. So net content of the raw material is :- 376000 Bottles * 15 ML * 350.88 MG = 1978.96 Kgs.))	376000.0 Numbers	2	Metamizole Magnesium	1776.60 Kg

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

Case No.	28 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006429AM24
RA File Number	092404000365 AM20
Licence No and Date	0910068207/20/11/2019
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	29 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023

and Date											
HQ File Number	HQRNORM REVIW00002001AM24										
RA File Number	092404000540 AM20										
Licence No and Date	0910068421/28/01/2020										
Norms Committee Decision:											
Dr. Suresh Reddy Childipudi, R&D Head, and Shri T. Ram Prasad of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed</th></tr><tr><td>(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride</td><td>1 kg.</td><td>1</td><td>CDX-034 LYOPHILIZED ENZYME POWDER</td><td>0.014 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.014 kg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed							
(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.014 kg							
RA concerned may take further necessary action as per above decision of Norms Committee.											

Case No.	30 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005893AM24
RA File Number	039504000017 AM21
Licence No and Date	0310835789/21/04/2020
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	31 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00007119AM23
RA File Number	052404000024 AM21
Licence No and Date	0510414104/04/05/2020
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Broxinac Eye Drops 0.09% 2.5 ml /100 Vials Bromfenac Eye Drops 0.09% 2.5ml		1	Bromfenac Sodium Hydrate	263.925 mg.
Broxinac Eye Drops 0.09% 1.7 ml /100 Vials Bromfenac Eye Drops 0.09% 1.7ml		2	Bromfenac Sodium Hydrate	179.469 mg

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

Case No.	32 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	OLIVE HEALTH CARE
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00007206AM23
RA File Number	039504000069 AM21
Licence No and Date	0310836213/15/05/2020

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 Item	Qty. allowed
1	TEMAZEPAM TEVA 10 MG CAPSULES (TEMAZEPAM CAPSULES 10MG)((TOTAL NO OF CAPSULES IS 10725000 AND NET WT OF EXEMPT MATERIALS CONTAIN IN RESULTANT PRODUCT IS 107 KG))	1 Number	1	TEMAZEPAM Ph.Eur.	10.20 mg
2	TEMAZEPAM TEVA 20 MG CAPSULES (TEMAZEPAM	1 Number	2	TEMAZEPAM Ph.Eur.	20.40 mg

	CAPSULES 20 MG)((TOTAL NO OF CAPSULES IS 12187500 AND NET WT OF EXEMPT MATERIALS CONTAIN IN RESULTANT PRODUCT IS 244 KG))				
RA concerned may take further necessary action as per above decision of NC.					

Case No.	33 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006254AM24
RA File Number	082404000394 AM20
Licence No and Date	0810147815/22/05/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jan/202223/18 dated 23.01.2023** against advance authorization No. **0811006083 dated 22.09.2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg per ML Oral Drop of 5 ML.(NET CONTENTS OF METAMIZOLE MAGNESIUM IS 324 KGS.)	216000 Numbers	1	Metamizole Magnesium	344.769 Kg
2	Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg per ML Oral Drops of 15 ML.(NET CONTENTS OF METAMIZOLE MAGNESIUM IS 5076 KGS.)	1128000 Numbers	2	Metamizole Magnesium	5329.792 Kg

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

Case No.	34 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000095AM24
RA File Number	522404000013 AM21
Licence No and Date	5210043424/08/06/2020
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and it was decided to call for following information/documents from the firm:- i. Complete chemical reactions with molecular and structural formula and molecular weight alongwith stage wise percentage yield on molar basis. ii. All technical details as per annexure to appendix 4E for chemical products. iii. Step wise manufacturing process.	

Case No.	35 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005894AM24
RA File Number	039504000137 AM21
Licence No and Date	0310836741/18/06/2020
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	36 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000121AM24
RA File Number	318304000020 AM21
Licence No and Date	3110067788/08/07/2020
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less :-	

Sl. No.	Export Product	Qty.	Sl. No.	Import Item	Qty. allowed
1	Mono Methyl Ether of Hydroquinone - MEHQ	1 Kg	1	Phenol	0.97 kg
			2	Methanol	0.38 kg
			3	Hydrogen Peroxide PURITY 60%	0.75 kg
			4	Acetone (Solvent)	0.10 kg

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

Case No.	37 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001550AM24
RA File Number	092404000185 AM21
Licence No and Date	0910068991/22/07/2020

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed
(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.014 kg

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

Case No.	38 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SHIVA BIO CHEM INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001904AM24
RA File Number	502404000009 AM21
Licence No and Date	5010002703/07/08/2020

Norms Committee Decision:

The Committee considered the request of firm for fixation of adhoc norms and it was 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	Sunflower Lecithin Powder	1 MT	1	Crude Sunflower Lecithin Liquid	1.40 MT
2	Rapeseed Lecithin Powder	1MT	2	Crude Rapeseed Lecithin Liquid	1.40 MT

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

Case No.	39 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006169AM24
RA File Number	039404000421 AM21
Licence No and Date	0310838377/21/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.13/82-ALC4/2018 dated 14/01/2019** against advance authorization **No. 0310818881 dated 05/02/2018**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	SODIUM CROMOGLICATE EYE 1 Vial DROPS 13.5 ML, 2% w/v	1	1	SODIUM CROMOGLYCAT	0.2835 gm/13.5 ml pack
2	SODIUM CROMOGLICATE EYE 1 Vial DROPS 10 ML, 2% w/v	1	1	SODIUM CROMOGLYCAT	0.210 gm/10 ml pack
3	SODIUM CROMOGLICATE EYE 1 Vial DROPS 5 ML, 2% w/v	1	1	SODIUM CROMOGLYCAT	0.105 gm/5 ml pack

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

Case No.	40 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00004763AM23
RA File Number	039404000500 AM21
Licence No and Date	0310839257/02/11/2020

Norms Committee Decision:

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

Sl.No	Export Product	Quantity
1	SECURA EXTRA PROTECTIVE CREAM 3.25 Oz 92 GM	1 Number
2	SECURA EXTRA PROTECTIVE CREAM 7.75 Oz 219.70 GM	1 Number
3	SECURA ANTIFUNGAL EXTRA THICK PROTECTIVE CREAM 3.25 Oz 92 GM	1 Number

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

Note:

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

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

Case No.	41 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00007267AM23
RA File Number	052404000395 AM21
Licence No and Date	0510415782/09/11/2020
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	42 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001504AM24
RA File Number	09AA04002748 AM21

Licence No and Date	0911000023/15/12/2020			
Norms Committee Decision:				
Dr. Suresh Reddy Childipudi, R&D Head, and Shri T. Ram Prasad of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed
Sodium (S)-4-oxo-4,6,7,8-tetrahydropyrrolo[1,2-a]pyrimidine-6-carboxylate(drug intermediate)	1 kg.	1	NORBORNADIENE TECH	2.00 kg.
RA concerned may take further necessary action as per above decision of Norms Committee.				

Case No.	43 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000254AM24
RA File Number	03AA04011698 AM21
Licence No and Date	0311000235/21/12/2020
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	44 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001514AM24
RA File Number	09AA04003656 AM21
Licence No and Date	0911000173/11/01/2021
Norms Committee Decision:	
Dr. Suresh Reddy Childipudi, R&D Head, and Shri T. Ram Prasad of the firm had attended the Personal Hearing	

and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed
(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.014 kg

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

Case No.	45 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005982AM24
RA File Number	038504000144 AM21
Licence No and Date	0311000450/25/02/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	46 / NC/3/MEET/Dec/202324/17				
Case Status	Case Approved				
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023				
HQ File Number	HQRNORM REVIW00001336AM24				
RA File Number	31AA04007907 AM21				
Licence No and Date	3111000255/30/03/2021				
Norms Committee Decision:					
The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less :-					
Sl. No.	Export product	Qty.	Sl.	Import items	Qty.

			No.		
1	AMINO ETHYL PIPERAZINE	1 Kg	1	MONO ETHANOL AMINE	1.261 Kg

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

Case No.	47 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006255AM24
RA File Number	08AA04005671 AM22
Licence No and Date	0811001621/01/06/2021

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/Jan/202223/18 dated 23.01.2023** against advance authorization No. **0811006083 dated 22.09.2022**, it was decided to fix adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Metamizaole Magnesium 300 mg and Pargerverine Hydrochloride 6mg Oral Drop((Considering the loss on drying @14.50 PERCENT of Bulkdrug for 300MG we need to poor 350.88 Mg. So net content of the raw material is :- 32500 Bottles X 5 ML X 350.88 MG = 57.02 Kgs.))	32500 Numbers	1	Metamizole Magnesium	51.875 Kg
2	Metamizaole Magnesium 300 mg and Pargerverine Hydrochloride 6mg Oral Drop((Considering the loss on drying @14.50 PERCENT of Bulkdrug for 300MG we need to poor 350.88 Mg. So net content of the raw material is :- 1074880 Bottles X 15 ML X 350.88 MG = 5657.31 Kgs.))	1074880 Numbers	2	Metamizole Magnesium	5078.800 Kg

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

Case No.	48 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	RUMIT LIFE CARE
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006332AM24
RA File Number	03AA04018136 AM22
Licence No and Date	0311004214/01/06/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. **NC/3/MEET/Aug/202324/11 dated 22/08/2023** against advance authorization No. **0311004279 dated 03/06/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Betamethasone Dipropionate (Net Content Betamethasone 17 Propionate BP/EP/USP = 100 kgs)(Betamethasone Dipropionate (Net Content Betamethasone 17 Propionate BP/EP/USP = 100 kgs))	1 kg.	1	Betamethasone 17 Propionate	0.94 kg.

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

Case No.	49 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001319AM24
RA File Number	03AA04017165 AM22
Licence No and Date	0311004253/02/06/2021

Norms Committee Decision:

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

Sl. No	Export Product	Quantity
1	Medical Ointments/Creams(Hydrocortisone 1 Percentage OTC Cream 1 OZ/ 28 gm Tube Total Wt.: 3998.79kg (Net Contents: Hydro39.99 kg, Glyc79.98, White wax119.97kg, Stea39.99kg, Iso319.90kg, Cetyl119.97kg, Sorb119.97kg, Poly119.97kg, Anhy2.80kg, Sod4.80kg, Sor2kg, Poly40 19.99))	1 Number
2	Medical Ointments/Creams(Hydrocortisone 1 Percentage OTC Ointment 1 OZ/ 28 gm Tube Total Wt.: 3799.96kg (Net Contents: Hydro38 Kg, White Petrolatum: 3685.97 Kg))	1 Number
3	Medical Ointments/Creams(Hydrocortisone Aloe 1 Percentage Cream 1 OZ/28 gm Tube Total Wt.: 2199.99kg (Net Contents: Hydro22kg, Glyc44kg, White wax66kg, Stea22kg, Iso176kg, Cetyl66kg, Sorb66kg, Poly66kg, Anhy1.54kg, Sod2.64kg, Sor1.10kg, Poly40 11kg, Aloe 2.20kg))	1 Number

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

Note:

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

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

Case No.	50 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	RUMIT LIFE CARE
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006331AM24
RA File Number	03AA04021934 AM22
Licence No and Date	0311004279/03/06/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Aug/202324/11** dated **22/08/2023** against advance authorization **No. 0311004279 dated 03/06/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Betamethasone Dipropionate (Net Content Betamethasone 17 Propionate BP/EP/USP = 100 kgs)(Betamethasone Dipropionate (Net Content Betamethasone 17 Propionate BP/EP/USP = 100 kgs))	1 kg.	1	Betamethasone 17 Propionate	0.94 kg.

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

Case No.	51 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001333AM24
RA File Number	03AA04018281 AM22
Licence No and Date	0311004321/04/06/2021

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 5 Gm Tube Total Wt: 146.34Kg, (Net Contents: Beta 0.18 Kg, Ceto 10.54 Kg, Fusidic 2.93 Kg, Macro 2.63 Kg, Empty Aluminium Tubes 29268 Nos)	1 Number
2	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 15 Gm Tube Total Wt: 600 Kg, (Net Contents: Beta 0.73 Kg, Ceto 43.20 Kg, Fusidic 12 Kg, Macro 10.80 Kg, Empty Aluminium Tubes 40000 Nos)	1 Number
3	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 30 Gm Tube Total Wt: 7185.30 Kg, (Net Contents: Beta 8.72 Kg, Ceto 517.34 Kg, Fusidic 143.71 Kg, Macro 129.34 Kg, Empty Aluminium Tubes 239510 Nos)	1 Number
4	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 60 Gm Tube Total Wt: 3424.38 Kg, (Net Contents: Beta 4.41 Kg, Ceto 261.35 Kg, Fusidic 72.60 Kg, Macro 65.34 Kg, Empty Aluminium Tubes 57643.73 Nos)	1 Number

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

Note:

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

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

Case No.	52 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001323AM24
RA File Number	03AA04015087 AM22
Licence No and Date	0311004561/12/06/2021

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medicinal Creams & Ointments(Permethrin Cream 5 Percentage (60 Gm) Total Wt: 18000Kgs (Net Contents : Permethrin Ph. Eur : 900Kg, Medium Chain : 1800Kg, Mono & DI- Glycerides : 900Kg, Isopropyl : 180Kg, Lanolin: 270Kg, Polyoxyethylene : 720Kg, Empty Tubes: 300000Nos))	1 Number

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

Note:

- i. 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**
- ii. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**

iii. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	53 / NC/3/MEET/Dec/202324/17
Case Status	Case Rejected
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006428AM24
RA File Number	09AA04003251 AM22
Licence No and Date	0911001059/16/06/2021
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	54 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00122419AM22
RA File Number	34AA04003768 AM22
Licence No and Date	3411000762/23/06/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	55 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006410AM24
RA File Number	09AA04004589 AM22
Licence No and Date	0911001093/23/06/2021
Norms Committee Decision:	

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

Sl. No.	Export Product	Qty.	S.No.	Import Item	Qty. allowed
1	Tobramycin for Inhalation solution 60 mg / ml (300 mg / 5 ml)	Number	1	Tobramycin Sulfate	466.49 mg / vial
2	Tobramycin for Inhalation solution 75 mg / ml (300 mg / 4 ml)	Number	2	Tobramycin Sulfate	466.49 mg / vial

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

Case No.	56 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005688AM23
RA File Number	08AA04009431 AM22
Licence No and Date	0811001850/25/06/2021

Norms Committee Decision:

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

Sl. No.	Export Product	Qty.	Sl.No.	Import Item	Qty. allowed
1	Indoline	1 Kg	1	O-CHLOROBENZYL CYANIDE	2.20 kg.
			2	TOLUENE	1.00 kg.

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

Case No.	57 / NC/3/MEET/Dec/202324/17
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Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00004361AM24
RA File Number	34AA04002140 AM22
Licence No and Date	3411000771/28/06/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	58 / NC/3/MEET/Dec/202324/17	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023	
HQ File Number	HQRNORM REVIW00001194AM24	
RA File Number	03AA04024851 AM22	
Licence No and Date	0311004989/29/06/2021	
Norms Committee Decision:		
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms for export to US only are as under:-		

Note:

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

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

Case No.	59 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001292AM24
RA File Number	03AA04035672 AM22
Licence No and Date	0311005214/08/07/2021

Norms Committee Decision:

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

Sl. No.	Export Product	Quantity
1	Medical Creams/Ointments(SECURA EXTRA PROTECTIVE CREAM 3.25 Oz 92 GM Total Wt. 14296.70 (Net Wt. White Petr 5835.91 Kg, Cetostearyl 874.96Kg, Glucate 729.13 Kg, Akucell 437.48Kg, Karaya Gum 1020.78Kg, Diazolidinyl 28.59Kg))	1 Number
2	Medical Creams/Ointments(SECURA EXTRA PROTECTIVE CREAM 7.75 Oz 219.70 GM Total Wt. 5567.24 (Net Wt. White Petr 2272.55Kg, Cetostearyl 340.71Kg, Glucate 283.93Kg, Akucell 170.36Kg, Karaya Gum 397.50Kg, Diazolidinyl 11.13Kg))	1 Number

3	Medical Creams/Ointments(SECURA ANTIFUNGAL EXTRA THICK PROTECTIVE CREAM 3.25 Oz 92 GM Total Wt. 2000 (Net Wt. White Petr 800Kg, Cetostearyl 120Kg, Glucate 100Kg, Akucell 60Kg, Karaya Gum 140Kg, Diazolidinyl 4Kg))	1 Number
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S.No	Import Product	Quantity
1	Relevant Bulk Drugs	Net content in the export product plus 3% wastage.
2	Relevant Excipients	Net content in the export product plus 3% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy

Note:

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

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

Case No.	60 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00137048AM22
RA File Number	34AA04005105 AM22
Licence No and Date	3411000838/12/07/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	61 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001310AM24
RA File Number	03AA04025361 AM22
Licence No and Date	0311005326/12/07/2021

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical Creams/Ointments(Ozonol Ointment 60 Gm Tube Total Wt. 1000.02 Kgs (Net Content BEES WAX YELLOW (REFINED) USP 72 Kgs, PHARMALAN (LANOLIN) USP 86.90 Kgs, ICHTHAMMOL USP 2.90 Kgs, ORIGANUM OIL RED IMITATION C IN HOUSE 4.10 Kgs, Empty Aluminium Collap Tube 16667 Nos))	1 Number

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

Note:

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

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

Case No.	62 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001518AM24
RA File Number	09AA04007265 AM22
Licence No and Date	0911001194/12/07/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed
(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg.	1	CDX-034 LYOPHILIZED ENZYME POWDER	0.014 kg

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

Case No.	63 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001313AM24
RA File Number	03AA04027532 AM22
Licence No and Date	0311005407/15/07/2021

Norms Committee Decision:

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

S.No.	Export Product	Quantity
1	Medical Creams/ Ointments(Miconazole Nitrate 2 Percentage Antifungal Cream 0.5 Oz / 14 Gm Total Wt: 406 Kg (Net Cont: Benzoic 0.81Kg, Pegoxyl 81.20Kg, Oleoyl 12.18Kg, Miconazole 8.33 Kg))	1 Number
2	Medical Creams/ Ointments(Miconazole Nitrate 2 Percentage Antifungal Cream 1 Oz / 28 Gm Total Wt: 2800 Kg (Net Cont: Benzoic 5.60Kg, Pegoxyl 560Kg, Oleoyl 84Kg, Miconazole 57.40Kg))	1 Number
3	Medical Creams/ Ointments(Miconazole Nitrate 2 Percentage Antifungal Cream 1.5 Oz / 42.5 Gm Total Wt: 397.16 Kg (Net Cont: Benzoic 0.79Kg, Pegoxyl 79.43Kg, Oleoyl 11.91Kg, Miconazole 8.14 Kg))	1 Number
4	Medical Creams/ Ointments(Miconazole Nitrate 2 Percentage Vaginal Cream USP 1.59 Oz / 45 Gm with 1 Applicator Pack Total Wt: 1200.11 Kg (Net Cont: Benzoic 2.40Kg, Pegoxyl 240.02Kg, Oleoyl 36Kg, Miconazole 24.60 Kg, Plastic app 26376 Nos))	1 Number
5	Medical Creams/ Ointments(Miconazole Nitrate 2 Percentage Vaginal Cream USP 1.59 Oz / 45 Gm with 7 Applicator Pack Total Wt: 35200.48Kg (Net Cont: Benzoic 70.40Kg, Pegoxyl 7040.10Kg, Oleoyl 1056.01Kg, Miconazole 721.61Kg, Plastic app 773637Nos))	1 Number

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

Note:

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

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

Case No.	64 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001316AM24
RA File Number	03AA04060052 AM22
Licence No and Date	0311006318/22/08/2021

Norms Committee Decision:

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

Sl.No	Export Product	Quantity
1	Medical Creams/Ointments(Clobetasol Propionate Ointment 0.05 percentage 15Gm Net Wt: 2499.98 Kgs (Net Cont: Clobetasole 1.29 Kg, Sorbitan 12.5 Kg, White Petrolatum 2361.23 Kg, Empty Tubes 166665 Nos))	1 Number
2	Medical Creams/Ointments(Clobetasol Propionate Ointment 0.05 percentage 30Gm Net Wt: 499.98 Kgs (Net Cont: Clobetasole 0.26 Kg, Sorbitan 2.5 Kg, White Petrolatum 472.23 Kg, Empty Tubes 16666 Nos))	1 Number
3	Medical Creams/Ointments(Clobetasol Propionate Ointment 0.05 percentage 45Gm Net Wt: 999.99 Kgs (Net Cont: Clobetasole 0.52 Kg, Sorbitan 5 Kg, White Petrolatum 944.49Kg, Empty Tubes 22222 Nos))	1 Number
4	Medical Creams/Ointments(Clobetasol Propionate Ointment 0.05 percentage 60Gm Net Wt: 10499.94 Kgs (Net Cont: Clobetasole 5.44 Kg, Sorbitan 52.5 Kg, White Petrolatum 9917.19 Kg, Empty Tubes 174999 Nos))	1 Number

S.No	Import Product	Quantity
1	Relevant Bulk Drugs	Net content in the export product plus 3% wastage.
2	Relevant Excipients	Net content in the export product plus 3% wastage.

3	Relevant Packaging Material	Relevant as per Packing Policy
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Note:

i. 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**

ii. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**

iii. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	65 / NC/3/MEET/Dec/202324/17	
Case Status	Case Approved	
Party Name	ENCUBE ETHICALS PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023	
HQ File Number	HQRNORM REVIW00001363AM24	
RA File Number	03AA04063825 AM22	
Licence No and Date	0311006317/22/08/2021	
Norms Committee Decision:		
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms for export to US only are as under:-		

1	Relevant Bulk Drugs	Net content in the export product plus 3% wastage.
2	Relevant Excipients	Net content in the export product plus 3% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy

Note:

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

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

Case No.	66 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001317AM24
RA File Number	03AA04060785 AM22
Licence No and Date	0311006386/24/08/2021

Norms Committee Decision:

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

Sl. No	Export Product	Quantity
1	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 10 Gm tubeLabelled content Clotrimazole 1 Percentage W/W Brand Canesten or any other. Tot Wt. 6060Kgs (Net Cont: Clotri 60.60Kgs, Oct 818.10Kgs, Cetyl 181.80Kgs, Ceto 606Kgs, Emp tubes	1 Number

	606000Nos)	
2	Medical Creams & Ointments(Clotrimazole 1 Percentage Vaginal cream 35Gm Tube with 6 ApplicatorLabelled content Clotrimazole1 Percentage W/W Brand Canesten or any otherTot Wt.2999Kgs (Net Cont:Clotri30Kgs, Oct404.98Kgs, Cetyl90Kgs, Ceto299.99Kgs, Tubes 85710Nos, Plas 514260No))	1 Number
3	Medical Creams & Ointments(Clotrimazole1 PercentageCream 100 Gm Tube Labelled content Clotrimazole1 Percentage W/W Brand Canesten or any other Tot Wt.2000Kgs (Net Cont:Clotri20Kgs, Oct270Kgs, Cetyl60Kgs, Ceto200Kgs, Tubes20000Nos))	1 Number
4	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 20Gm.Tube Labelled content Clotrimazole1 PercentageW/W Brand Canesten or any otherTot Wt.9660Kgs (Net Cont:Clotri96.60Kgs, Oct1304.10Kgs, Cetyl289.80Kgs, Ceto966Kgs, Tubes483000Nos))	1 Number
5	Medical Creams & Ointments(Clotrimazole 1 PercentageCream 50 Gm.Tube Labelled content Clotrimazole1 PercentageW/W Brand Canesten or any other.Tot Wt.12910Kgs (Net Cont:Clotri129.10Kgs, Oct1742.85Kgs, Cetyl387.30Kgs, Ceto1291Kgs, Tubes 258200Nos))	1 Number
6	Medical Creams & Ointments(Clotrimazole 2 Percentage Vaginal Cream 20 Gm.Tube with 3 ApplicatorLabelled content Clotrimazole 2 PercentageW/W Brand Canesten or any other.Tot Wt.3000Kgs (Net Cont:Clotri60Kgs, Oct405Kgs, Cetyl90Kgs, Ceto300Kgs, Tubes 150000Nos, Plas 450000No)	1 Number
7	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 5 Gm.Tube Labelled content Clotrimazole 1 Percentage W/W Brand Canesten or any other.Tot Wt.1500Kgs (Net Cont:Clotri15Kgs, Oct202.50Kgs, Cetyl45Kgs, Ceto150Kgs, Tubes300000Nos))	1 Number
8	Medical Creams & Ointments(Clotrimazole 1 Percentage Cream 3 Gm. Tube Labelled content Clotrimazole 1 Percentage W/W Brand Canesten or any otherTot Wt.1500Kgs (Net Cont:Clotri15Kgs, Oct202.50Kgs, Cetyl45Kgs, Ceto150Kgs, Tubes 500000Nos))	1 Number
9	Medical Creams & Ointments(Clotrimazole 1 Percentage cream 10 Gm. Tube with Fluconazole Capsule Labelled content clotrimazole 1 Percentage W/W Brand Canesten or any otherTot Wt.370Kgs(Net Cont:Clotri3.70Kgs, Oct49.95Kgs,Cetyl111.1Kgs,Ceto37Kgs, Tubes 37000Nos))	1 Number
S.No	Import Product	Quantity

1	Relevant Bulk Drugs	Net content in the export product plus 3% wastage.
2	Relevant Excipients	Net content in the export product plus 3% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy

Note:

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

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

Case No.	67 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001355AM24
RA File Number	03AA04068130 AM22
Licence No and Date	0311006626/01/09/2021

Norms Committee Decision:

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

Sl.No	Export Product	Quantity
1	Medical Creams & Ointments(Ketoconazole Cream 2 percentage, 15 gm Total Wt: 5528.32 Kg (Net Cont: Sorb 110.57Kg, Poly 82.92Kg, Stearyl 414.62Kg, Isopropyl 55.28Kg, Tube: 368555Nos))	1 Number

2	Medical Creams & Ointments(Ketoconazole Cream 2 percentage, 30 gm Total Wt: 12207.03Kg (Net Cont: Sorb 666.03Kg, Poly 499.52Kg, Stearyl 2497.60Kg, Isopropyl 333.01Kg, Tube: 555023Nos))	1 Number
3	Medical Creams & Ointments(Ketoconazole Cream 2 percentage, 60 gm Total Wt: 33301.37 Kg (Net Cont: Sorb 666.03Kg, Poly 499.52Kg, Stearyl 2497.60Kg, Isopropyl 333.01Kg, Tube: 555023Nos))	1 Number

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

Note:

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

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

Case No.	68 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001356AM24
RA File Number	03AA04074695 AM22
Licence No and Date	0311006805/08/09/2021
Norms Committee Decision:	

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

Sl.No	Export Product	Quantity
1	Medicals Creams & Ointments(Desonide Ointment 0.05 Percenatge (15 Gm) Tot Wt. 990 Kg, (Net Cont: Desonide 0.508 Kg, White Petrolatum 989.51 Kg, Empty Tubes 66000 Nos))	1 Number
2	Medicals Creams & Ointments(Desonide Ointment 0.05 Percenatge (60 Gm) Tot Wt. 2220 Kg, (Net Cont: Desonide 1.14 Kg, White Petrolatum 2218.89 Kg, Empty Tubes 37000 Nos))	1 Number

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

Note:

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

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

Case No.	69 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001343AM24
RA File Number	03AA04010926 AM22
Licence No and Date	0311006852/10/09/2021

Norms Committee Decision:

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

Sl.No	Export Product	Quantity
1	Medicals & Ointments(CLOTRIMAZOLE 1 Percentage (10MG/G) ANTI FUNGAL CREAM Total Contents: 1880 Kg (Net Contents Clotrimazole 19.18 Kg, Cetyl Esters Wax 75.20 Kg))	1 Number
2	Medicals & Ointments(CLOTRIMAZOLE 1 PERCENTAGE (10MG/G) VAGINAL CREAM Total Contents: 3290 Kg (Net Contents Clotrimazole 33.56 Kg, Cetyl Esters Wax 131.60 Kg))	1 Number

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

Note:

- i. 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**
- ii. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**

iii. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	70 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001468AM24
RA File Number	34AA04006805 AM22
Licence No and Date	3411001099/10/09/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dimetol((2,6-Dimethylheptan-2-ol))	1 kg.	1	6 Methyl 2 heptanone	0.98 kg.
		2	Acetic acid	0.18 kg.

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

Case No.	71 / NC/3/MEET/Dec/202324/17
Case Status	Case Rejected
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00183041AM22
RA File Number	03AA04090257 AM22
Licence No and Date	0311006909/13/09/2021

Norms Committee Decision:

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

Case No.	72 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00193597AM22
RA File Number	03AA04097753 AM22
Licence No and Date	0311007198/25/09/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	73 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	NATURAL AND ESSENTIAL OILS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
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 decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Caffeine(Powder)	9450 kg.	1	Crude Caffeine decaffeination from green coffee Purity 53.27%	17600 kg.
Coffee Extracts(Powder)	6250 kg.	2	Crude Caffeine decaffeination from green coffee Purity 53.27%	17600 kg.
Caffeine(Powder)	9250 kg.	3	Crude Caffeine decaffeination from green coffee Purity 52.12%	17600 kg.
Coffee Extracts(Powder)	6150 kg.	4	Crude Caffeine decaffeination from green coffee Purity 52.12%	17600 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	74 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006071AM24
RA File Number	03AA040106642 AM22
Licence No and Date	0311007268/28/09/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	75 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001306AM24
RA File Number	03AA040109530 AM22
Licence No and Date	0311007595/08/10/2021
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms for export to US only are as under:-	

1	Relevant Bulk Drugs	Net content in the export product plus 3% wastage.
2	Relevant Excipients	Net content in the export product plus 3% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy

Note:

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

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

Case No.	76 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001328AM24
RA File Number	03AA040109754 AM22
Licence No and Date	0311007605/10/10/2021

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical Creams & Ointments(Permethrin Cream 5 Percentage (60 Gm) Tot Wt: 34998.72 Kgs (Net Cont: Medium Chain 3499.87 Kgs, Mono & DI-Glycerides 1749.94 Kgs, Isopropyl 349.99 Kgs, Lanolin 524.98 Kgs, Polyoxyethylene 1399.95 Kgs, Tubes 583312 Nos))	1 Number

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

Note:

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

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

Case No.	77 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001293AM24
RA File Number	03AA040110377 AM22
Licence No and Date	0311007674/13/10/2021

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical Creams & Ointments(SECURA EXTRA PROTECTIVE CREAM 3.25 Oz 92 GM Tot Wt: 14296.70 Kgs (Net Cont: White Pet 5835.91Kgs, Ceto 874.95Kgs, Methyl 729.13Kgs, Akucell 437.47Kgs, Karaya 1020.78kgs, Diaz 28.59 Kgs))	1 Number
2	Medical Creams & Ointments(SECURA EXTRA PROTECTIVE CREAM 7.75 Oz 219.70 GM Tot Wt: 5567.24 Kgs (Net Cont: White Pet 2272.55Kgs, Ceto 340.71Kgs, Methyl 283.93Kgs, Akucell 170.36Kgs, Karaya 397.50kgs, Diaz 11.13 Kgs))	1 Number
3	Medical Creams & Ointments(SECURA ANTIFUNGAL EXTRA THICK PROTECTIVE CREAM 3.25 Oz 92 GM Tot Wt: 2000 Kgs (Net Cont: White Pet 800Kgs, Ceto 120Kgs, Methyl 100Kgs, Akucell 60Kgs, Karaya 140kgs, Diaz 4Kgs))	1 Number
4	Medical Creams & Ointments(SECURA EXTRA PROTECTIVE CREAM 90 GMS TUBE Tot Wt: 7842.96Kgs (Net Cont: White Pet 3201.50Kgs, Ceto 479.99Kgs, Methyl 399.99Kgs, Akucell 239.99Kgs, Karaya 559.99kgs, Diaz 15.69Kgs))	1 Number

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

Note:

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

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

Case No.	78 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00220580AM22
RA File Number	05AA04091063 AM22
Licence No and Date	0511005553/21/10/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	79 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00220582AM22
RA File Number	05AA04091028 AM22
Licence No and Date	0511005555/21/10/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	80 / NC/3/MEET/Dec/202324/17				
Case Status	Case Approved				
Party Name	CIPLA LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023				
HQ File Number	HQRNORM REVIW00002990AM24				
RA File Number	03AA040110548 AM22				
Licence No and Date	0311007891/25/10/2021				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jan/202122/13 dated 21/01/2022 against advance authorization No.0311005784 dated 01/08/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. allowed
1	Telmisartan and Amlodipine Tablets 40/10mg / Each uncoated tablets contains :(Telmisartan 40 mg	1 Number	1	Telmisartan Granules	68.034 mg

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

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

Case No.	81 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001361AM24
RA File Number	03AA040115878 AM22
Licence No and Date	0311008179/02/11/2021
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms for export to US only are as under:-	

S.No	Export Product	Quantity
1	Medical Creams & Ointments(Myoflex Regular Strength 10 percentage 100 Gm Tube Tot Wt: 2000Kgs (Net Cont: Cetyl 200Kgs, Stearyl 100Kgs, Bess Wax 20Kgs, Trolamine 104.80 Kgs, Oil 0.44 Kgs))	1 Number
2	Medical Creams & Ointments(Myoflex Extra Strength 15 percentage 100 Gm Tube Tot Wt: 3000Kgs (Net Cont: Cetyl 300Kgs, Stearyl 150Kgs, Bess Wax 30Kgs, Trolamine 235.80 Kgs, Oil 0.66 Kgs))	1 Number
3	Medical Creams & Ointments(Myoflex Maximum Strength 20 percentage 100 Gm Tube Tot Wt: 5000Kgs (Net Cont: Cetyl 550Kgs, Stearyl 275Kgs, Bess Wax 55Kgs, Trolamine 524 Kgs, Oil 1.10 Kgs))	1 Number

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

Note:

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

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

Case No.	82 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AARTI INDUSTRIES LTD
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023

and Date	
HQ File Number	HQRNORM APPLY 00246187AM22
RA File Number	03AA04078980 AM22
Licence No and Date	0311008372/09/11/2021
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- i. Percentage Yield on molar basis for each step and justification thereof. ii. Requirement and recovery of Tartaric Acid and Monoglyme and their Net consumption. iii. Copy of Technical Literature in support of (i) above.	

Case No.	83 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006176AM24
RA File Number	03AA040119771 AM22
Licence No and Date	0311008387/10/11/2021
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	84 / NC/3/MEET/Dec/202324/17										
Case Status	Case Approved										
Party Name	SENTISS PHARMA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023										
HQ File Number	HQRNORM REVIW00007115AM23										
RA File Number	05AA04097736 AM22										
Licence No and Date	0511006029/10/11/2021										
Norms Committee Decision:											
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Broxinac Eye Drops 0.09% 2.5 ml /100 Vials Bromfenac Eye Drops 0.09% 2.5ml</td><td></td><td>1</td><td>Bromfenac Sodium Hydrate</td><td>263.925 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Broxinac Eye Drops 0.09% 2.5 ml /100 Vials Bromfenac Eye Drops 0.09% 2.5ml		1	Bromfenac Sodium Hydrate	263.925 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Broxinac Eye Drops 0.09% 2.5 ml /100 Vials Bromfenac Eye Drops 0.09% 2.5ml		1	Bromfenac Sodium Hydrate	263.925 mg.							

Broxinac Eye Drops 0.09% 1.7 ml /100 Vials Bromfenac Eye Drops 0.09% 1.7ml		1	Bromfenac Sodium Hydrate	179.469 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	85 / NC/3/MEET/Dec/202324/17
Case Status	Case Rejected
Party Name	HELLA INFRA MARKET PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00255252AM22
RA File Number	03AA040117899 AM22
Licence No and Date	0311008615/17/11/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm has still not furnished the reply of DL. Hence, the Committee decided to reject the case.	

Case No.	86 / NC/3/MEET/Dec/202324/17
Case Status	Case Rejected
Party Name	HELLA INFRA MARKET PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00255254AM22
RA File Number	03AA040120188 AM22
Licence No and Date	0311008616/17/11/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm has still not furnished the reply of DL. Hence, the Committee decided to reject the case.	

Case No.	87 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001304AM24
RA File Number	03AA040120589 AM22
Licence No and Date	0311008617/17/11/2021
Norms Committee Decision:	

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

S. No	Export Product	Quantity
1	Medical Creams & Ointments(Miconazole Nitrate 2 % Antifungal Cream 0.5 Oz / 14 Gm Tot Wt: 203 Kgs (Net Cont: Benzoic 0.41 Kgs, Pegoxyl 40.60 Kgs, Oleoyl 6.09 Kgs, Miconazole 4.16 Kgs))	1 Number
2	Medical Creams & Ointments(Miconazole Nitrate 2 % Antifungal Cream 1 Oz / 28 Gm Tot Wt: 1400 Kgs (Net Cont: Benzoic 2.80 Kgs, Pegoxyl 280 Kgs, Oleoyl 41 Kgs, Miconazole 28.70 Kgs))	1 Number
3	Medical Creams & Ointments(Miconazole Nitrate 2 % Antifungal Cream 1.5 Oz / 42.5 Gm Tot Wt: 397.16 Kgs (Net Cont: Benzoic 0.79 Kgs, Pegoxyl 79.43 Kgs, Oleoyl 11.91 Kgs, Miconazole 8.14 Kgs))	1 Number
4	Medical Creams & Ointments(Miconazole Nitrate 2 % Vaginal Cream USP 1.59 Oz / 45 Gm with 1 Applicator Pack Tot Wt: 10282.95 Kgs (Net Cont: Benzoic 20.57 Kgs, Pegoxyl 2056.59 Kgs, Oleoyl 308.49 Kgs, Miconazole 210.80 Kgs, Plas App 228510 Nos))	1 Number
5	Medical Creams & Ointments(Miconazole Nitrate 2 % Vaginal Cream USP 1.59 Oz / 45 Gm with 7 Applicator Pack Tot Wt: 45103.23 Kgs (Net Cont: Benzoic 90.21 Kgs, Pegoxyl 9020.65 Kgs, Oleoyl 1353.10 Kgs, Miconazole 924.62 Kgs, Plas App 1002294 Nos))	1 Number

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

Note:

- i. 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**
- ii. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**

iii. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	88 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	SARACA LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00256800AM22			
RA File Number	09AA04017459 AM22			
Licence No and Date	0911001876/18/11/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Aug/202223/6 dated 09/09/2023 against advance authorization No.0911002446 dated 04/02/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GABAPENTIN(API)	1 kg.	1	1,1 CYCLOHEXANE DI ACETIC ACID MONOAMIDE (CAM)	1.630 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	89 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ARKRAY HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
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 request of firm for fixation of ad-hoc norms and it was decided to call for following	

information/documents from the firm:-

1. **Technical process flow diagram of manufacturing of Parahit-F Device Test Kit involving imported items and wastage involved at each step.**
2. **Batch manufacturing record and material issued and material reconciliation sheet for production of a batch, duly signed by dealing QA/Executive/Manager.**

Drug Manufacturing License (DML).

Case No.	90 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005985AM24
RA File Number	03AA04013560 AM22
Licence No and Date	0311008775/23/11/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	91 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005991AM24
RA File Number	03AA04014060 AM22
Licence No and Date	0311008817/24/11/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	92 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005993AM24
RA File Number	03AA04003343 AM22
Licence No and Date	0311008815/24/11/2021

Norms Committee Decision:

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

Case No.	93 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005994AM24
RA File Number	03AA04009051 AM22
Licence No and Date	0311008816/24/11/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	94 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001344AM24
RA File Number	03AA040124209 AM22
Licence No and Date	0311009064/01/12/2021

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical Creams & Ointments(Clobetasol Propionate Ointment 0.05% 15Gm Tot Wt: 2499.98 Kgs (Net Cont Clobetasol 1.29Kgs, Sorbitan 12.50Kgs, White Petrolatum 2361.23Kgs, Tubes 166665Nos))	1 Number
2	Medical Creams & Ointments(Clobetasol Propionate Ointment 0.05% 30Gm Tot Wt: 499.98 Kgs (Net Cont Clobetasol 0.26Kgs, Sorbitan 2.50Kgs, White Petrolatum 472.23Kgs, Tubes 16666Nos))	1 Number
3	Medical Creams & Ointments(Clobetasol Propionate Ointment 0.05% 45Gm Tot Wt: 999.99 Kgs (Net Cont Clobetasol 0.52Kgs, Sorbitan 5Kgs, White Petrolatum 944.49Kgs, Tubes 22222Nos))	1 Number

4	Medical Creams & Ointments(Clobetasol Propionate Ointment 0.05% 60Gm Tot Wt: 10499.94Kgs (Net Cont Clobetasol 5.44Kgs, Sorbitan 52.50Kgs, White Petrolatum 9917.19Kgs, Tubes 174999Nos))	1 Number
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S.No	Import Product	Quantity
1	Relevant Bulk Drugs	Net content in the export product plus 3% wastage.
2	Relevant Excipients	Net content in the export product plus 3% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy

Note:

i. 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**

ii. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US.**

iii. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	95 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005995AM24
RA File Number	03AA04014502 AM22
Licence No and Date	0311009117/02/12/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	96 / NC/3/MEET/Dec/202324/17
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Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001345AM24
RA File Number	03AA040124200 AM22
Licence No and Date	0311009326/09/12/2021

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05% 15 Gm tube Tot Wt: 1500 (Net Cont: Clob 0.78 Kg, Arlcel 67.50Kg, White Wax 15, Tubes 100000 Nos))	1 Number
2	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05% 30 Gm tube Tot Wt: 2250 (Net Cont: Clob 1.17 Kg, Arlcel 101.25Kg, White Wax 22.50, Tubes 75000 Nos))	1 Number
3	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05% 45 Gm tube Tot Wt: 1750.05 (Net Cont: Clob 0.91 Kg, Arlcel 78.75Kg, White Wax 17.50, Tubes 38890 Nos))	1 Number
4	Medical Creams & Ointments(Clobetasol Propionate Cream 0.05% 60 Gm tube Tot Wt: 2999.88 (Net Cont: Clob 1.56 Kg, Arlcel 135Kg, White Wax 30, Tubes 49998 Nos))	1 Number

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

Note:

- i. 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**

ii. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US**.

iii. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	97 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00283907AM22
RA File Number	09AX04000009 AM22
Licence No and Date	0911002042/13/12/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Carbonic Acid 4-Nitrophenyl-5-1 kg. Thiazolylmethyl Ester		1	2-Chloro-5- (Chloromethyl)thiazole	1.25 kg.

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

Case No.	98 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00287478AM22
RA File Number	03AA040122138 AM22
Licence No and Date	0311009510/16/12/2021
Norms Committee Decision:	

Shri Kunal Sikchi, Director and Shri Nitin Vyas, Sr. Executive of the firm had attended the Personal Hearing and explained firm's case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Oct/202122/9 dated 15/10/2021** against advance authorization **No. 0310837496dated 30/07/2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Sl. No.	Export Product	Qty.
1	Phytosterol Natural Refined Phytosterol 95%	60,000.0 kg.
2	Natural Mixed Tocopherol 50%	38,500.0kg.

Sl. No.	Import Item	Qty.
1	Fatty Acid Distillate / Deoderised Distillate	9,21,250 kg.
2	Acetone	44,000 kg.
3	N-HEPTANE	94,050 kg.

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

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

Case No.	99 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001321AM24
RA File Number	03AA040130524 AM22
Licence No and Date	0311009529/16/12/2021

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical Creams & Ointments(Hydrocortisone 1% OTC Cream 1 OZ/ 28 gm Tube Tot Wt 4191.66 Kgs Net Cont:(In KGs)Hydro: 41.92, Glyceryl 83.83,Wax 125.75,Stearyl41.92,Isopropyl 335.33,Cetyl125.75, Sorbitan125.75,Polysorb 125.75,Anhydrous2.93,Sodium5.03,Sorbic2.10, polyoxyl 20.96)	1 Number
2	Medical Creams & Ointments(Hydrocortisone 1 Percentage OTC Ointment 1 OZ/ 28 gm Tube (Net Cont: Hydrocortisone USP (Micronized) 20.00 Kgs))	1 Number
3	Medical Creams & Ointments(Hydrocortisone Aloe 1% Cream 1 OZ/28 gm Tube Net Cont: (In KGs) Hydrocort 40, Glyceryl Stearate 80, White wax 120, Stearyl 40, Isopropyl 320, Cetyl 120, Sorbitan120, Polysorb 120, Anhydrous 2.8, Sodium 4.8, sorbic acid 2, Polyoxyl 20, Aloe 4.)	1 Number

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

Note:

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

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

Case No.	100 / NC/3/MEET/Dec/202324/17
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Case Status	Case Approved
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00293142AM22
RA File Number	05AX04000189 AM22
Licence No and Date	0511007079/21/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in **meeting No. NC/3/MEET/Nov/202324/16 dated 17/11/2023** against advance authorization **No.0511006681 dated 07/12/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CEFEPIME POWDER FOR SOLUTION FOR INJECTION, WEIGHT 1 GMS/VIAL (CEFEPIME HCL+LARGININE STERILE USP)	1 Number	1	CEFEPIME HCL+L-ARGININE STERILE USP	1.05 gm.
EFEPIME POWDER FOR SOLUTION FOR INJECTION,WEIGHT 2 GMS/VIAL (CEFEPIME HCL+LARGININE STERILE USP)	1 Number	2	CEFEPIME HCL+L-ARGININE STERILE USP	2.10 gm.

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

Case No.	101 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00293146AM22
RA File Number	34AX04000029 AM22
Licence No and Date	3411001569/21/12/2021

Norms Committee Decision:

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

Case No.	102 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001346AM24
RA File Number	03AA040123994 AM22
Licence No and Date	0311009655/21/12/2021

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 15 Gm Tube)	1 Number
2	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 30 Gm Tube)	1 Number
3	Medical Creams & Ointments(Fusidic Acid and Betamethasone Valerate Cream 60 Gm Tube)	1 Number
4	Medical Creams & Ointments(Fusidic Acid Cream 15 Gm Tube)	1 Number
5	Medical Creams & Ointments(Fusidic Acid Cream 30 Gm Tube)	1 Number

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

Note:

- i. 1.03 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments **solely for export to US.**

ii. 1.02 kg. of bulk drug and excipients may be allowed per kg. content of bulk drug and excipients in the export of Medicinal Cream/Ointments for the export to **other than US**.

iii. The firm will declare net weight of import items (Relevant Bulk Drugs and Excipients) in export to the RA concerned for redemption.

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

Case No.	103 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001357AM24
RA File Number	03AX04000252 AM22
Licence No and Date	0311009654/21/12/2021

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical Creams & Ointments(Desonide Ointment 0.05 % (15 Gm) Tot Wt: 975Kgs (Net Cont: Desonide 0.5Kgs, White Petrolatum 974.51Kgs, Tubes: 65000Nos))	1 Number
2	Medical Creams & Ointments(Desonide Ointment 0.05 % (60 Gm) Tot Wt: 1350Kgs (Net Cont: Desonide 0.69Kgs, White Petrolatum 1349.33Kgs, Tubes: 22500Nos))	1 Number

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

Note:

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

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

Case No.	104 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001329AM24
RA File Number	03AX04000251 AM22
Licence No and Date	0311009744/24/12/2021

Norms Committee Decision:

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

S.No.	Export Product	Quantity
1	Medical Creams & Ointments(Permethrin Cream 5 % (60 Gm) Tot Wt: 35998.56Kgs (Net Cont: Medium chain 3599.86Kgs, Mono 1799.93Kgs, Isopropyl 359.99Kgs, Lanolin 539.98Kgs, Polyoxy 1439.94Kgs, Tubes 599976Nos))	1 Number

S.No	Import Product	Quantity
1	Relevant Bulk Drugs	Net content in the export product plus 3% wastage.

2	Relevant Excipients	Net content in the export product plus 3% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy

Note:

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

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

Case No.	105 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001354AM24
RA File Number	03AX04000229 AM22
Licence No and Date	0311009746/24/12/2021

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical Creams & Ointments(Ketoconazole Cream 2 percentage, 15 gm Tot Wt: 4999.97Kgs (Net Cont: Sorbitan 100Kgs, Poly 75Kgs, Stearyl 375Kgs, Isopropyl 50Kgs, Tubes 333331Nos))	1 Number
2	Medical Creams & Ointments(Ketoconazole Cream 2 percentage, 30 gm Tot Wt: 12999.87Kgs (Net Cont: Sorbitan 260Kgs, Poly 195Kgs, Stearyl 974.99Kgs, Isopropyl	1 Number

	130Kgs, Tubes 433329Nos))	
3	Medical Creams & Ointments(Ketoconazole Cream 2 percentage, 60 gm Tot Wt: 37999.62Kgs (Net Cont: Sorbitan 759.99Kgs, Poly 569.99Kgs, Stearyl 2849.97Kgs, Isopropyl 380Kgs, Tubes 633327Nos))	1 Number

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

Note:

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

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

Case No.	106 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006188AM24
RA File Number	03AX04000256 AM22
Licence No and Date	0311009818/27/12/2021
Norms Committee Decision:	

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

Case No.	107 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00299896AM22
RA File Number	34AX04000090 AM22
Licence No and Date	3411001598/28/12/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	108 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006305AM24
RA File Number	08AX04000140 AM22
Licence No and Date	0811003577/28/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in **meeting No. NC/3/MEET/Jan/202223/18 dated 23/01/2023** against advance authorization **No.0811006083 dated 22/09/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Metamizaole Magnesium 300 mg and Pargerverine Hydrochloride 6mg Oral Drop (Considering the loss on drying @14.50% of Bul (Metamizaole Magnesium 300 mg and Pargerverine Hydrochloride 6mg Oral Drop (Considering the loss on drying @14.50% of Bulkdrug for 300MG we need to poor 350.88 Mg. So net content of the raw material is :-90000 Bottles * 5 ML * 350.88 MG = 157.89 Kgs.))	90000 Numbers	1	Metamizole Magnesium	143.654 kg.
Metamizaole Magnesium 300 mg and	1150000	2	Metamizole Magnesium	5433.742 kg.

Pargeverine Hydrochloride 6mg Oral Drop (Considering the loss on drying @14.50% of Bul(Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop (Considering the loss on drying @14.50% of Bulkdrug for 300 MG we need to poor 350.88 Mg. So net content of the raw material is :-1150000 Bottles * 15 ML * 350.88 MG = 6052.68 K)	Numbers			
RA concerned may take further necessary action as per above decision of NC.				

Case No.	109 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	KRUNAL INDUSTRIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00301989AM22
RA File Number	08AX04000162 AM22
Licence No and Date	0811003592/30/12/2021
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Percentage yield of reaction. 2. Stichometric balance on Molar basis plus percentage yield to arrive at the quantity of raw material asked. 3. Quantity and commercial value of By-product obtained.	

Case No.	110 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000165AM24
RA File Number	03AX04000308 AM22
Licence No and Date	0311009920/30/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal	

Hearing before Norms Committee to explain its case alongwith following information / documents from the firm :-

- i. **Molar Weight of each input and output item of each stage.**
- ii. **Percentage yield on molar basis for each step.**
- iii. **CA certified Production/Consumption data.**
- iv. **Sample of Shipping Bills and Bill of Entry of the export products along with statement of Input-output as per export documents of the said authorization.**

Case No.	111 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	PANACEA BIOTEC PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005946AM24
RA File Number	05AX04000321 AM22
Licence No and Date	0511007823/11/01/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	112 / NC/3/MEET/Dec/202324/17										
Case Status	Case Approved										
Party Name	ZYDUS LIFESCIENCES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023										
HQ File Number	HQRNORM APPLY 00317040AM22										
RA File Number	08AX04000199 AM22										
Licence No and Date	0811003776/13/01/2022										
Norms Committee Decision:											
Shri Vimal Kaneria, General Manager, Shri Mahek Shah, Manager (Exim) & Logistics and Shri Devendra Mali, Manager (Corporate Affairs) of the firm had attended the Personal Hearing and explained firm’s case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms on the basis of information provided by the firm, it was decided to fix ad-hoc norms as under, or as applied whichever is lower: -											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed</th></tr><tr><td>MEMANTINE HYDROCHLORIDE</td><td>1 Number</td><td>1</td><td>MEMANTINE HYDROCHLORIDE USP</td><td>7.14 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	MEMANTINE HYDROCHLORIDE	1 Number	1	MEMANTINE HYDROCHLORIDE USP	7.14 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed							
MEMANTINE HYDROCHLORIDE	1 Number	1	MEMANTINE HYDROCHLORIDE USP	7.14 mg.							

EXTENDED RELEASE CAPSULES 7 MG ((ACTIVE INGREDIENT: MEMANTINE HYDROCHLORIDE USP - NET WT. 22.40 KGS.))		2	SUGAR SPHERES (NON-PAREIL) NF	30.60 mg.
		3	HYPROMELLOSE 5 CPS 2910 USP	3.824 mg.
		4	HYPROMELLOSE 3 CPS 2910 USP	3.06 mg.
		5	TRIETHYL CITRATE NF	0.829 mg.
		6	TALC PH EUR/USP	1.594 mg.
MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 14 MG ((ACTIVE INGREDIENT: MEMANTINE HYDROCHLORIDE USP - NET WT. 72.78 KGS.))	1 Number	7	MEMANTINE HYDROCHLORIDE USP	14.28 mg.
		8	SUGAR SPHERES (NON-PAREIL) NF	61.20 mg.
		9	HYPROMELLOSE 5 CPS 2910 USP	7.648 mg.
		10	HYPROMELLOSE 3 CPS 2910 USP	6.12 mg.
		11	TRIETHYL CITRATE NF	1.658 mg.
		12	TALC PH EUR/USP	3.188 mg.
MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 21 MG ((ACTIVE INGREDIENT: MEMANTINE HYDROCHLORIDE USP - NET WT. 67.19 KGS.))	1 Number	13	MEMANTINE HYDROCHLORIDE USP	21.42 mg.
		14	SUGAR SPHERES (NON-PAREIL) NF	91.80 mg.
		15	HYPROMELLOSE 5 CPS 2910 USP	11.472 mg.
		16	HYPROMELLOSE 3 CPS 2910 USP	9.18 mg.
		17	TRIETHYL CITRATE NF	2.487 mg.
		18	TALC PH EUR/USP	4.782 mg.
MEMANTINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES 28 MG ((ACTIVE INGREDIENT: MEMANTINE HYDROCHLORIDE USP - NET WT. 568.34 KGS.))	1 Number	19	MEMANTINE HYDROCHLORIDE USP	28.56 mg.
		20	SUGAR SPHERES (NON-PAREIL) NF	122.40 mg.
		21	HYPROMELLOSE 5 CPS 2910 USP	15.296 mg.

		22	HYPROMELLOSE 3 CPS 2910 USP	12.24 mg.
		23	TRIETHYL CITRATE NF	3.316 mg.
		24	TALC PH EUR/USP	6.376 mg.
MEMANTINE HYDROCHLORIDE 1 Number TABLETS 5 MG((ACTIVE INGREDIENT: MEMANTINE HYDROCHLORIDE USP - NET WT. 160.98 KGS.))		25	MEMANTINE HYDROCHLORIDE USP	5.10 mg.
		26	TALC PH EUR/USP	1.02 mg.
		27	CROSCARMELLOSE SODIUM NF	5.61 mg.
		28	DIBASIC CALCIUM PHOSPHATE DIHYDRATE USP	73.95 mg.
		29	MAGNESIUM STEARATE PH.E/NF/JP	1.02 mg.
MEMANTINE HYDROCHLORIDE 1 Number TABLETS 10 MG ((ACTIVE INGREDIENT: MEMANTINE HYDROCHLORIDE USP - NET WT. 229.96 KGS.))		30	MEMANTINE HYDROCHLORIDE USP	10.20 mg.
		31	TALC PH EUR/USP	2.04 mg.
		32	CROSCARMELLOSE SODIUM NF	11.22 mg.
		33	DIBASIC CALCIUM PHOSPHATE DIHYDRATE USP	147.90 mg.
		34	MAGNESIUM STEARATE PH.E/NF/JP	2.04 mg.

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

Case No.	113 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001606AM24
RA File Number	31AX04000040 AM22
Licence No and Date	3111000876/14/01/2022
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
AMINO ETHYL PIPERAZINE (ORGANIC CHEMICAL)	1 kg.	1	MONO ETHANOL AMINE	1.261 kg.
ETHYLENEDIAMINE (ORGANIC CHEMICAL)	1 kg.	2	MONO ETHANOL AMINE	1.06 kg.
		3	AMMONIA ANHYDROUS	0.294 kg.
DI ETHYLENE TRI AMINE (ORCGANIC CHEMICAL)	1 kg.	4	MONO ETHANOL AMINE	1.184 kg.
		5	AMMONIA ANHYDROUS	0.165 kg.
PIPERAZINE (ORGANIC CHEMICAL)	1 kg.	6	MONO ETHANOL AMINE	1.481 kg.
AMINO ETHYL ETHANOL AMINE (ORGANIC CHEMICAL)	1 kg.	7	MONO ETHANOL AMINE	1.173 kg.

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

Case No.	114 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005988AM24
RA File Number	03AX04000043 AM22
Licence No and Date	0311010585/17/01/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	115 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006478AM23
RA File Number	03AX04001106 AM22
Licence No and Date	0311011140/06/02/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2,5-DIMERCAPTO-1,3,4-THIADIAZOLE(YALUB DMTD)	1 kg.	1	HYDRAZINE HYDRATE	0.4125kg.
		2	CAUSTIC SODA	0.266 kg.
		3	CARBON DISULPHIDE	0.048 kg.

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

Case No.	116 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00351303AM22
RA File Number	09AX04000191 AM22
Licence No and Date	0911002504/11/02/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import item in meeting **No.NC/3/MEET/Oct/202324/15 dated 13/10/2023** against advance authorization **No.0911001978 dated 13/12/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

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

1-[(3R,4S)-4-Cyanotetrahydropyran-3-yl]-3-[(2-fluoro-6-methoxy-4-pyridyl)amino]pyrazole-4-carboxamide((L-005251026-Form-I)	1 kg.	1	Ethyl-3-amino-1-4-cyanotetrahydro-2H-pyran-3-yl)-1H-Pyrazole-4-carboxylate (Racemic ECPC)	5.120 kg.
		2	2-Fluoro-4-Iodo-6-Methoxy Pyridine (IFMP)	2.267 kg.
		3	4,5-bis(Diphenylphosphino)-9,9-dimethylxanthane (Xantphos)	0.153 kg.

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

Case No.	117 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00356332AM22
RA File Number	08AX04000424 AM22
Licence No and Date	0811004069/15/02/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BUSPIRONE HYDROCHLORIDE TABLETS USP 5 MG(EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 5 MG)	1 Number	1	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	5.1 mg / tablet
BUSPIRONE HYDROCHLORIDE TABLETS USP 7.5 MG(EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 7.5 MG)	1 Number	2	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	7.65 mg / tablet
BUSPIRONE HYDROCHLORIDE TABLETS USP 10 MG(EACH	1 Number	3	BUSPIRONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR.	10.2 mg / tablet

UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 10 MG)				
BUSPIRONE HYDROCHLORIDE TABLETS USP 15 MG(EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 15 MG)	Number	4	BUSPIRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR.	15.3 mg / tablet
BUSPIRONE HYDROCHLORIDE TABLETS USP 30 MG(EACH UNCOATED TABLET CONTAINS: BUSPIRONE HYDROCHLORIDE USP 30 MG [IN WHICH ACTIVE INGREDIENT BUSPIRONE HYDROCHLORIDE USED IS 459.500 KGS.])	Number	5	BUSPIRONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR.	30.6 mg / tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	118 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	EMCURE PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM REVIW00001969AM24			
RA File Number	31AX04000077 AM22			
Licence No and Date	3111001114/02/03/2022			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CIPROBIOTIC FORT TAB 500MG (CIPROFLOXACIN TABLETS 500MG) (EACH FILM COATED TABLET	1 Number	1	CIPROFLOXACIN HYDROCHLORIDE USP (Ciprofloxacin Hydrochloride Monohydrate)	582.21mg.

CONTAIN : CIPROFLOXACIN HYDROCHLORIDE USP EQUIVALENT TO CIPROFLOXACIN 500 MG [NET WEIGHT 2577.33 KG])				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	119 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006124AM24
RA File Number	08AX04000605 AM22
Licence No and Date	0811004316/08/03/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	120 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AARTI INDUSTRIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00386427AM22
RA File Number	03AX04001504 AM22
Licence No and Date	0311012791/14/03/2022
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. End-Use of the export item. 2. Complete and Balanced chemical reactions with molar weight and pertentage yield on molar basis for each step. 3. Step-wise Material balance showing requirement and recovery of Tetra Hydro Furan (THF).	

Case No.	121 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	AETHER INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023																			
HQ File Number	HQRNORM APPLY 00386506AM22																			
RA File Number	52AX04000090 AM22																			
Licence No and Date	5211002165/14/03/2022																			
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty</th> <th>S.No.</th> <th>Import Item</th> <th>Qty. allowed</th> </tr> </thead> <tbody> <tr> <td rowspan="3">3-METHOXY-2-METHYLENZOYL CHLORIDE.</td> <td rowspan="3">1 Kg</td> <td>1</td> <td>2,6-DICHLOROTOLUENE</td> <td>1.90 kg</td> </tr> <tr> <td>2</td> <td>TETRAHYDROFURAN</td> <td>1.50 kg</td> </tr> <tr> <td>3</td> <td>DIMETHYLSULFOXIDE</td> <td>1.37 kg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty	S.No.	Import Item	Qty. allowed	3-METHOXY-2-METHYLENZOYL CHLORIDE.	1 Kg	1	2,6-DICHLOROTOLUENE	1.90 kg	2	TETRAHYDROFURAN	1.50 kg	3	DIMETHYLSULFOXIDE	1.37 kg
Export Product	Qty	S.No.	Import Item	Qty. allowed																
3-METHOXY-2-METHYLENZOYL CHLORIDE.	1 Kg	1	2,6-DICHLOROTOLUENE	1.90 kg																
		2	TETRAHYDROFURAN	1.50 kg																
		3	DIMETHYLSULFOXIDE	1.37 kg																

Case No.	122 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006448AM24
RA File Number	03AX04000062 AM23
Licence No and Date	0311013759/11/04/2022
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and it was decided to call for following information/documents from the firm:- - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights 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.	

vi. Sample of shipping bills and bill of entry of the export products along with statement of Input-output as per export documents of the said authorization.

Case No.	123 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00000912AM23
RA File Number	09AX04000058 AM23
Licence No and Date	0911003033/20/05/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	124 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000608AM24
RA File Number	05AX04000553 AM23
Licence No and Date	0511012820/26/05/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	125 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005924AM23
RA File Number	03AX04001050 AM23
Licence No and Date	0311015297/07/06/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	126 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	BRAWN LABORATORIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006171AM23
RA File Number	05AX04000865 AM23
Licence No and Date	0511013337/21/06/2022
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Justificaton for enhancement in the quantity of import item.	

Case No.	127 / NC/3/MEET/Dec/202324/17				
Case Status	Case Approved				
Party Name	CIPLA LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023				
HQ File Number	HQRNORM REVIW00000259AM24				
RA File Number	03AX04001871 AM23				
Licence No and Date	0311015826/24/06/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jan/202122/13 dated 21/01/2022 against advance authorization No.0311005784 dated 01/08/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. allowed
1	Telmisartan and Amlodipine Tablets 40/10mg / Each uncoated tablets contains : Telmisartan 40 mg(Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is 2020.800 Kgs. Net wt of Amlodipine Besilate is 300.000 Kgs.)	1 Number	1	Telmisartan Granules	68.034 mg
			2	Amlodipine Besilate	10.20 mg
2	Telmisartan and Amlodipine Tablets 80/10mg / Each uncoated tablets contains : Telmisartan 80 mg(Telmisartan 80 mg equivalent to Telmisartan granules 134.72mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is 10777.600 Kgs. Net wt of Amlodipine Besilate is 800.000 Kgs.)	1 Number	3	Telmisartan Granules	136.07 mg
			4	Amlodipine Besilate	10.20 mg

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

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

Case No.	128 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005934AM23
RA File Number	34AX04000311 AM23
Licence No and Date	3411002472/01/07/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MELONAL (2,6-dimethylhept-5-enal) (Clear colorless liquid)	1 kg.	1	Methyl Heptenone	1.50 kg.
		2	Methyl Mono Chloro Acetate/ Ethyl Chloro Acetate	1.72 kg
		3	Sodium Methoxide	0.8711 kg.

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

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

Case No.	129 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006007AM23
RA File Number	03AX04001989 AM23
Licence No and Date	0311016055/04/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	130 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	KusuMa PharMa
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00000597AM24
RA File Number	03AX04002093 AM23
Licence No and Date	0311016291/12/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	131 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ASMEE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006476AM24
RA File Number	03AX04002471 AM23
Licence No and Date	0311016692/29/07/2022
Norms Committee Decision:	

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

1. **Complete chemistry, molecular weight and percentage yield on molar basis as per Annexure to Appendix 4E.**
2. **Application / Use of Export Product.**
3. **By Product, if any and its Commercial Value.**

Case No.	132 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00001228AM24
RA File Number	31AX04000136 AM23
Licence No and Date	3111001598/02/08/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ETHYLENEDIAMINE (ORGANIC CHEMICAL)	1 kg.	1	MONO ETHANOL AMINE	1.06 kg.
		2	AMMONIA ANHYDROUS	0.294 kg.
DI ETHYLENE TRI AMINE (ORGANIC CHEMICAL)	1 kg.	3	MONO ETHANOL AMINE	1.184 kg.
		4	AMMONIA ANHYDROUS	0.165 kg.
AMINO ETHYL ETHANOL AMINE (ORGANIC CHEMICAL)	1 kg.	5	MONO ETHANOL AMINE	1.173 kg.

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

Case No.	133 / NC/3/MEET/Dec/202324/17
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Case Status	Case Deferred
Party Name	METROPOLITAN EXIMCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002481AM23
RA File Number	03AX04002332 AM23
Licence No and Date	0311016872/04/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	134 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002501AM23
RA File Number	03AX04002642 AM23
Licence No and Date	0311016913/05/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	135 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006414AM24
RA File Number	09AX04000207 AM23
Licence No and Date	0911003443/05/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	136 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002512AM23
RA File Number	03AX04002601 AM23
Licence No and	0311017009/08/08/2022

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No.0311013777 dated 11/04/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ROSUVASTATIN CALCIUM	1 kg.	1	Tert-Butyl(E)-(6-(2-(4-(4-fluorophenyl)-6-Isopropyl-2-(Methyl(Methyl Sulfonyl) Amino Pyrimidin-5-yl)Vinyl)(4R,6S)-2,2-Dim	1.30 kg.
		2	ETHYL ACETATE	0.674 kg.
		3	METHANOL	1.874 kg.
		4	TOLUENE	0.772 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	137 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	GLENMARK LIFE SCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00002513AM23			
RA File Number	03AX04002600 AM23			
Licence No and Date	0311017010/08/08/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.5/82-ALC4/2015 dated 25/06/2015 against advance authorization No.0310792671 dated 08/01/2015, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

OLMESARTAN MEDOXOMIL	1 kg.	1	4-(1-HYDROXY-1-METHYL ETHYL)-2- PROPYL-1H-IMIDAZOLE 5- CARBOXYLIC ACID ETHYL ESTER	0.70 kg.
		2	5-(4-BROMOMETHYL) (1,- BROMOMETHYLIPHENYL)-2YL TRIPHENYL-1-H TETRAZOLE; 5-(4?- BROMOMETHYL BIPHENYL-2-YL)-1- TRITYL-1H-TET	1.35 kg.
		3	4-CHLOROMETHYL-5-METHYL 1,3- DIOXOLEN-2-ONE	0.426 kg.
		4	METHYLENE CHLORIDE (MDC)	5.32 kg.
		5	TOLUENE	2.73 kg.
		6	DIMETHYL FORMAMIDE (DMF)	1.95 kg.

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

Case No.	138 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002518AM23
RA File Number	07AX04000655 AM23
Licence No and Date	0711004861/08/08/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Nifuroxazide	1 kg.	1	5-Nitro-2-furohydrazide	0.634 kg.

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

Case No.	139 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	PRACHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002520AM23
RA File Number	08AX04000754 AM23
Licence No and Date	0811005702/08/08/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRIAMCINOLONE ACETONIDE BP/EP/USP((9?-Fluoro-11?,21- dihydroxy-16?,17- isopropylidenedioxy-1,4- pregnadiene-3,20-dione))	1 kg.	1	3TR (TETRAENE ACETATE)	1.00 kg.

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

Case No.	140 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002528AM23
RA File Number	08AX04000709 AM23
Licence No and Date	0811005708/08/08/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Nov/202324/16 dated 17/11/2023** against advance authorization **No.0811004766 dated 23/04/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NALTREXONE HYDROCHLORIDE TABLETS 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE PH. EUR. 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 309.000 KGS.])	1 Number	1	NALTREXONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR (Alcoholic Solvents and water content not less than 1.86% as per CoA of import item)	51.93 mg / tablet

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

Case No.	141 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002546AM23
RA File Number	03AX04002602 AM23
Licence No and Date	0311017046/10/08/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TELMISARTAN	1 kg.	1	2N-PROPYL-4-METHYL-6-(1-METHYL-BENZIMIDAZOL-2-YL)BENZIMIDAZOLE	0.621 kg.
		2	4-METHYL-2-BIPHENYL CARBOXYLIC ACID METHYL ESTER	0.60 kg.
		3	METHANOL	3.69 kg.
		4	METHYLENE CHLORIDE	2.20 kg.
		5	ACETIC ACID GLACIAL	0.90 kg.

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

Case No.	142 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002548AM23
RA File Number	03AX04002511 AM23
Licence No and Date	0311017048/10/08/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Please get the Advance Authorisation amended to show content of API in export in line with DML.	

Case No.	143 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ALCHEMIE FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002553AM23
RA File Number	03AX04002069 AM23
Licence No and Date	0311017059/10/08/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	144 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002560AM23
RA File Number	34AX04000414 AM23
Licence No and Date	3411002630/10/08/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	145 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002566AM23
RA File Number	30AX04000206 AM23
Licence No and Date	3011002481/10/08/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Aug/202324/11 dated 22/08/2023** against advance authorization **No. 3011001471 dated 06/12/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
VINORELBINE SOLUTION FOR INJECTION (50MG/5ML) (1 ML OF SOLUTION CONTAINS: VINORELBINE TARTRATE , EQUIVALENT TO VINORELBINE10MG EXCIPIENTS: TARTARIC ACID, WATER FOR INJECTION)	1 Vial	1	VINORELBINE TARTRATE	69.00 mg.

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

Case No.	146 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	RAKSHIT PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002581AM23
RA File Number	09AX04000400 AM23
Licence No and Date	0911003458/10/08/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Aug/202324/11 dated 22/08/2023** against advance authorization **No.0911002001 dated 06/12/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Mycophenolate Sodium (solid)	1 kg.	1	Mycophenolic Acid	0.90 kg.
		2	Toluene	0.66 kg.
		3	Methanol	0.70 kg.

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

Case No.	147 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002596AM23
RA File Number	34AX04000442 AM23
Licence No and Date	3411002639/11/08/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PARA NITRO TOLUENE	1 kg.	1	NITRIC ACID 68 PERCENT	0.6636 kg.
		2	TOLUENE	0.661 kg.
		3	SULPHURIC ACID 98 PERCENT	Indigenous
		4	SODA ASH	Indigenous

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

Case No.	148 / NC/3/MEET/Dec/202324/17
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Case Status	Case Deferred
Party Name	GUJARAT FLUOROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002598AM23
RA File Number	34AX04000342 AM23
Licence No and Date	3411002640/11/08/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- - 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. - Sample of shipping bills and bill of entry of the export products along with statement of Input-output as per export documents of the said authorization.	

Case No.	149 / NC/3/MEET/Dec/202324/17													
Case Status	Case Approved													
Party Name	EPIGRAL LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023													
HQ File Number	HQRNORM APPLY 00002599AM23													
RA File Number	34AX04000456 AM23													
Licence No and Date	3411002641/11/08/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202223/24 dated 13/04/2023 against advance authorization No.3411001842 dated 23/02/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>EPICHLOROHYDRIN (1-Chloro-2,3-epoxypropane)</td><td>1 kg.</td><td>1</td><td>REFINED GLYCERINE 99 PERCENT MIN</td><td>1.0206 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	EPICHLOROHYDRIN (1-Chloro-2,3-epoxypropane)	1 kg.	1	REFINED GLYCERINE 99 PERCENT MIN	1.0206 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
EPICHLOROHYDRIN (1-Chloro-2,3-epoxypropane)	1 kg.	1	REFINED GLYCERINE 99 PERCENT MIN	1.0206 kg.										

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

Case No.	150 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002645AM23
RA File Number	03AX04002727 AM23
Licence No and Date	0311017254/16/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	151 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SUVEN PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002650AM23
RA File Number	09AX04000426 AM23
Licence No and Date	0911003473/16/08/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202223/24 dated 13/04/2023** against advance authorization **No. 0911002860 dated 19/04/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,2,3,5-TETRA-O-ACETYL-B-L-RIBOFURANOSE (POWDER)	1 kg.	1	METHYL ISO BUTYL KETON	1.840 kg.
		2	L RIBOSE	0.842 kg.

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

Case No.	152 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved

Party Name	EPIGRAL LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00002655AM23			
RA File Number	34AX04000449 AM23			
Licence No and Date	3411002647/16/08/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
EPICHLOROHYDRIN (1-Chloro-2,3-epoxypropane)	1 kg.	1	CRUDE GLYCERINE 80 PERCENT MIN	1.27 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	153 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	KLJ PLASTICIZERS LIMITED.			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00002668AM23			
RA File Number	05AX04001382 AM23			
Licence No and Date	0511014320/17/08/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DI-ISO DECYL ADIPATE (DIDA)(DI-ISO DECYL ADIPATE (DIDA) (PACKED IN 477 NOS. OF HM-HDPE DRUMS MADE OF HDPE GRANULES (4,054.500 KGS. WITHOUT WASTAGE)) (EACH DRUM	1 kg.	1	ADIPIC ACID	0.35 kg.
		2	ISO DECANOL	0.768 kg.
		3	HDPE GRANULES (TOTAL WEIGHT = 4,257.225 KGS.)	Relevant as per packing policy.

SHALL WEIGHT 8.5 KG AND STORAGE CAPACITY 210.000 KGS.)				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	154 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002693AM23
RA File Number	07AX04000739 AM23
Licence No and Date	0711005063/19/08/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
FERROUS FORTE TABLETS (FERROUS FORTE TABLETS (Vitamin C (as Ascorbic Acid) -71mg (177.500 KGS) +Iron (From Ferrous BisglycinateChelate- 126mg (315.00 KGS) With Other Essential Vitamins & Minerals (No of Tabs-2500000))	1 Number	1	ASCORBIC ACID DC 97 Percentage -SF. I.H	63.087 mg.
		2	IRON BISGLYCINATE	122.400 mg

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

Case No.	155 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002758AM23
RA File Number	08AX04000605 AM23

Licence No and Date	0811005824/24/08/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Copy of DML with approved composition for each export item. 2. Justification for six import item in Appendix-4E vis-e-vis import item in Advance Authorisation.	

Case No.	156 / NC/3/MEET/Dec/202324/17																							
Case Status	Case Approved																							
Party Name	EUGIA PHARMA SPECIALITIES LIMITED																							
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023																							
HQ File Number	HQRNORM APPLY 00002764AM23																							
RA File Number	09AX04000315 AM23																							
Licence No and Date	0911003526/24/08/2022																							
Norms Committee Decision:																								
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																								
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 50ml - (40mg/1ml-50ml) i.e., 2000 mg/50ml (Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 50ml - (40mg/1ml-50ml) i.e.,2000mg/50ml))</td><td>1 Number</td><td>1</td><td>Gemcitabin Hydrochloride Ph.Eur</td><td>2.391 gm</td></tr><tr><td>Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 25ml - (40mg/1ml-25ml) i.e.,1000 mg /25ml (Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 25ml - (40mg/1ml-25ml) i.e.,1000mg/25ml))</td><td>1 Number</td><td>2</td><td>Gemcitabin Hydrochloride Ph.Eur</td><td>1.195 gm</td></tr><tr><td>Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 5ml - (40mg/1ml-5ml) i.e., 200mg /5ml)(Gemcitabine 40mg</td><td>1 Number</td><td>3</td><td>Gemcitabin Hydrochloride Ph.Eur</td><td>0.239 gm</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 50ml - (40mg/1ml-50ml) i.e., 2000 mg/50ml (Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 50ml - (40mg/1ml-50ml) i.e.,2000mg/50ml))	1 Number	1	Gemcitabin Hydrochloride Ph.Eur	2.391 gm	Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 25ml - (40mg/1ml-25ml) i.e.,1000 mg /25ml (Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 25ml - (40mg/1ml-25ml) i.e.,1000mg/25ml))	1 Number	2	Gemcitabin Hydrochloride Ph.Eur	1.195 gm	Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 5ml - (40mg/1ml-5ml) i.e., 200mg /5ml)(Gemcitabine 40mg	1 Number	3	Gemcitabin Hydrochloride Ph.Eur	0.239 gm
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																				
Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 50ml - (40mg/1ml-50ml) i.e., 2000 mg/50ml (Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 50ml - (40mg/1ml-50ml) i.e.,2000mg/50ml))	1 Number	1	Gemcitabin Hydrochloride Ph.Eur	2.391 gm																				
Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 25ml - (40mg/1ml-25ml) i.e.,1000 mg /25ml (Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 25ml - (40mg/1ml-25ml) i.e.,1000mg/25ml))	1 Number	2	Gemcitabin Hydrochloride Ph.Eur	1.195 gm																				
Gemcitabine 40mg concentrate for solution for intravenous infusion - fill volume 5ml - (40mg/1ml-5ml) i.e., 200mg /5ml)(Gemcitabine 40mg	1 Number	3	Gemcitabin Hydrochloride Ph.Eur	0.239 gm																				

concentrate for solution for intravenous infusion - fill volume 5ml - (40mg/1ml-5ml) i.e.,200mg/5ml)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	157 / NC/3/MEET/Dec/202324/17													
Case Status	Case Approved													
Party Name	WEST BENGAL CHEMICAL INDUSTRIES LTD.													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023													
HQ File Number	HQRNORM APPLY 00002765AM23													
RA File Number	02AX04000280 AM23													
Licence No and Date	0211002902/24/08/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>SODIUM BUTYRATET</td><td>1 kg.</td><td>1</td><td>N-BUTYRIC ACID</td><td>0.842 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	SODIUM BUTYRATET	1 kg.	1	N-BUTYRIC ACID	0.842 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
SODIUM BUTYRATET	1 kg.	1	N-BUTYRIC ACID	0.842 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	158 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AURORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002801AM23
RA File Number	09AX04000470 AM23
Licence No and Date	0911003541/26/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	159 / NC/3/MEET/Dec/202324/17			
Case Status	Case Deferred			

Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002813AM23
RA File Number	07AX04000768 AM23
Licence No and Date	0711005110/26/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	160 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002814AM23
RA File Number	03AX04002857 AM23
Licence No and Date	0311017519/27/08/2022

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical creams & Ointment(Ozonol Antibiotic Plus Pain Relief Ointment 30 Gm Tube (Tot Wt: 1999.98 Kgs Net Cont Bacitracin 15.94 Kgs,Polymyxin 2.84 Kgs, Aluminium Tubes 66666 Nos))	1 Number

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

Note:

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

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

Case No.	161 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	GODAVARI BIOREFINERIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002842AM23
RA File Number	03AX04002739 AM23
Licence No and Date	0311017558/29/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	162 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002857AM23
RA File Number	09AX04000483 AM23
Licence No and Date	0911003562/30/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	163 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023

HQ File Number	HQRNORM APPLY 00002871AM23
RA File Number	08AX04000919 AM23
Licence No and Date	0811005862/01/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	164 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	HI-PURITY CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002877AM23
RA File Number	03AX04002948 AM23
Licence No and Date	0311017592/01/09/2022
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. The firm has to give molecular weight of each chemical of reactants and products.	

Case No.	165 / NC/3/MEET/Dec/202324/17										
Case Status	Case Approved										
Party Name	AMI ORGANICS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023										
HQ File Number	HQRNORM REVIW00004178AM24										
RA File Number	52AX04001623 AM23										
Licence No and Date	5211003147/01/09/2022										
Norms Committee Decision:											
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>3,4 DI HYDROXY 5 NITRO BENZAL DEHYDE-99% min</td><td>1 kg.</td><td>1</td><td>VANILLINE- 99.5 % min (Tech. spec :powder)</td><td>1.588 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	3,4 DI HYDROXY 5 NITRO BENZAL DEHYDE-99% min	1 kg.	1	VANILLINE- 99.5 % min (Tech. spec :powder)	1.588 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
3,4 DI HYDROXY 5 NITRO BENZAL DEHYDE-99% min	1 kg.	1	VANILLINE- 99.5 % min (Tech. spec :powder)	1.588 kg.							

		2	DI METHYL FORMAMIDE - 99.5% (Tech. spec :Liquid)	3.17 kg.
		3	METHYLENE CHLORIDE (Tech. spec :Liquid)	2.40 kg.

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

Case No.	166 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	DIAMINES AND CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002917AM23
RA File Number	34AX04000464 AM23
Licence No and Date	3411002727/02/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Nov/202324/16 dated 17/11/2023** against advance authorization **No. 3411000885 dated 22/07/2021** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PIPERAZINE ANHYDROUS	1 kg.	1	PIPERAZINE CRUDE OR PIPERAZINE MIXTURE (Percentage purity not more than 48.1%)	2.047 kg.

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

Case No.	167 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002919AM23
RA File Number	34AX04000543 AM23
Licence No and	3411002729/02/09/2022

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

Case No.	168 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00002944AM23
RA File Number	07AX04000812 AM23
Licence No and Date	0711005159/05/09/2022
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- I. Manufacturing process indicating the grade of chemicals to use. II. Use of Potassium Carbonate Granular. . III. Reason for using Granular form of Potassium Carbonate.	

Case No.	169 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	RAJASTHAN ANTIBIOTICS LTD			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00002981AM23			
RA File Number	05AX04001405 AM23			
Licence No and Date	0511014704/07/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
KETOPROFEN BP (STERILE POWDER) (32.3% TO 39.5% W/W)	1 kg.	1	KETOPROFEN EP (Non-sterile)	0.363 kg.

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

Case No.	170 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003003AM23
RA File Number	03AX04002647 AM23
Licence No and Date	0311017727/08/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	171 / NC/3/MEET/Dec/202324/17																
Case Status	Case Approved																
Party Name	AUROBINDO PHARMA LTD																
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023																
HQ File Number	HQRNORM APPLY 00003018AM23																
RA File Number	09AX04000445 AM23																
Licence No and Date	0911003612/08/09/2022																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="3">Tazobactam ((Tazobactam Anhydrous) from Palladium on Charcoal route (US and Europe))</td><td rowspan="3">1 kg.</td><td>1</td><td>BENZHYDRYL 6,6-DIHYDROPENICILLANATE-1-OXIDE (or) (2S,5R)-3,3-DIMETHYL-7-OXO-4-THIA-1- AZABICYCLO [3.2.0]HEPTANE-2-CARBOXYL</td><td>4.8624 kg.</td></tr><tr><td>2</td><td>Methylene Chloride</td><td>10.76 kg.</td></tr><tr><td>3</td><td>Toluene</td><td>5.18 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Tazobactam ((Tazobactam Anhydrous) from Palladium on Charcoal route (US and Europe))	1 kg.	1	BENZHYDRYL 6,6-DIHYDROPENICILLANATE-1-OXIDE (or) (2S,5R)-3,3-DIMETHYL-7-OXO-4-THIA-1- AZABICYCLO [3.2.0]HEPTANE-2-CARBOXYL	4.8624 kg.	2	Methylene Chloride	10.76 kg.	3	Toluene	5.18 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Tazobactam ((Tazobactam Anhydrous) from Palladium on Charcoal route (US and Europe))	1 kg.	1	BENZHYDRYL 6,6-DIHYDROPENICILLANATE-1-OXIDE (or) (2S,5R)-3,3-DIMETHYL-7-OXO-4-THIA-1- AZABICYCLO [3.2.0]HEPTANE-2-CARBOXYL	4.8624 kg.													
		2	Methylene Chloride	10.76 kg.													
		3	Toluene	5.18 kg.													

		4	Dimethylformamide (DMF)	18.87 kg.
		5	Acetone	12.23 kg.
		6	Carbon Enoanticromos (Activated Carbon)	0.1292 kg.
		7	10% Palladium On Charcoal (Type: C-10110/CIII)	0.0136 kg.
		8	Methanol (Methyl Alcohol)	0.3119 kg.

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

Case No.	172 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003021AM23
RA File Number	34AX04000522 AM23
Licence No and Date	3411002756/09/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	173 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003029AM23
RA File Number	08AX04000798 AM23
Licence No and Date	0811005961/09/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No. 0811002393 dated 25/08/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 1ML VIAL(EACH ML CONTAINS: VINORELBINE TARTRATE PH.EUR EQ. TO VINORELBINE 10 MG)	1 Number	1	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR	14.33 mg.
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 5ML VIAL(EACH ML CONTAINS: VINORELBINE TARTRATE PH.EUR EQ. TO VINORELBINE 10 MG [IN WHICH ACTIVE INGREDIENT VINORELBINE TARTRATE USED IS 967.000 GRAMS])	1 Number	2	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR	71.66 mg.

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

Case No.	174 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003031AM23
RA File Number	08AX04000738 AM23
Licence No and Date	0811005966/09/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Nov/202324/16** dated **17/11/2023** against advance authorization **No. 0811004766 dated 23/04/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NALTREXONE HYDROCHLORIDE TABLETS 50 MG(EACH FILM COATED TABLET CONTAINS:	1 Number	1	NALTREXONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR (Alcoholic Solvent and water	51.93 mg / tablet

NALTREXONE HYDROCHLORIDE PH. EUR. 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 95.250 KGS.]			content not less than 1.86% as per CoA of import item).	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	175 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	INTIGREAT CONSULTING SERVICES LLP
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003056AM23
RA File Number	03AX04002543 AM23
Licence No and Date	0311017790/12/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	176 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	SAURAV CHEMICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00003058AM23			
RA File Number	30AX04000258 AM23			
Licence No and Date	3011002579/12/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Oct/202324/15 dated 13/10/2023 against advance authorization No.3011000867 dated 09/07/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
VILDAGLIPTIN	1 kg.	1	L PROLINAMIDE	0.768 kg.

		2	3 AMINO 1 ADAMANTANOL	0.769 kg.
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RA concerned may take further necessary action as per above decision of NC

Case No.	177 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003064AM23
RA File Number	05AX04001671 AM23
Licence No and Date	0511014757/12/09/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- As per chemistry given Benzyl Difluoromethyl Sulphide to give End product as such justification for import of both raw material.	

Case No.	178 / NC/3/MEET/Dec/202324/17										
Case Status	Case Approved										
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023										
HQ File Number	HQRNORM APPLY 00003065AM23										
RA File Number	31AX04000173 AM23										
Licence No and Date	3111001690/12/09/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 83.33% W/W WHITE GRANULES POWDER</td><td>1 kg.</td><td>1</td><td>DICYANDIAMIDE (DCDA) WHITE POWDER</td><td>0.47 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 83.33% W/W WHITE GRANULES POWDER	1 kg.	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.47 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 83.33% W/W WHITE GRANULES POWDER	1 kg.	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.47 kg.							

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

Case No.	179 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003092AM23
RA File Number	34AX04000422 AM23
Licence No and Date	3411002775/13/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	180 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003118AM23
RA File Number	09AX04000498 AM23
Licence No and Date	0911003623/14/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	181 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	MEGHMANI NOVOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003128AM23
RA File Number	08AX04000233 AM23
Licence No and Date	0811006022/15/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Oct/202324/15 dated 13/10/2023 against advance authorization No. 0811002298 dated 11/08/2021, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed
BCMB (Bis Chloro Methyl Biphenyl)	1 kg	1	Biphenyl	1.389 kg.
		2	Paraformaldehyde	1.0 kg.
		3	Zinc Chloride Anhydrous	1.0 kg.
		4	Methanol	0.889 kg.

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

Case No.	182 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003129AM23
RA File Number	08AX04000980 AM23
Licence No and Date	0811006023/15/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	183 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003134AM23
RA File Number	03AX04002730 AM23
Licence No and Date	0311017884/15/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202223/24 dated 13/04/2023 against advance authorization No.0311007732 dated 17/10/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Sl. No.	Export Product	Qty.
1	Mometasone Furoate Ointment 0.10 Percent (Pack 10gms) (Net Wt. of Mometasone Furoate Micronized 0.200 Kgs.)	20000 Numbers
2	Mometasone Furoate Ointment 0.10 Percent (Pack 15gms) (Net Wt. of Mometasone Furoate Micronized 0.300 Kgs.)	20000 Numbers
3	Mometasone Furoate Ointment 0.10 Percent /Mometasone Ointment 0.10 Percent (Pack 20gms) (Net Wt. of Mometasone Furoate Micro 0.400 Kgs.)	20000 Numbers
4	Mometasone Furoate Ointment 0.10 Percent (Pack 30gms) (Net Wt. of Mometasone Furoate Micronized 3.000 Kgs.)	100000Numbers
5	Mometasone Furoate Ointment 0.10 Percent (pack 45gms) (Net Wt. of Mometasone Furoate Micronized 4.50 Kgs.)	100000 Numbers
6	Mometasone Furoate Ointment 0.10 Percent (Pack 50gms) (Net Wt. of Mometasone Furoate Micronized 1.00 Kgs.)	20000 Numbers
7	Mometasone Furoate Ointment 0.10 Percent (pack 60gms) (Net Wt. of Mometasone Furoate Micronized 1.800 Kgs.)	30000 Numbers
8	Mometasone Furoate Ointment 0.10 Percent (pack 100gms) (Net Wt. of Mometasone Furoate Micronized 2.000 Kgs.)	20000 Numbers
9	Mometasone Furoate Tropical Solution USP 0.1 Percent (Lotion) (Pack 30ml) (Net Wt. of Mometasone Furoate Micronized 0.900 Kgs.)	30000 Numbers
10	Mometasone Furoate Tropical Solution USP 0.1 Percent (Lotion) (Pack 60ml) (Net Wt. of Mometasone Furoate Micronized 1.800 Kgs.)	30000 Numbers
11	Mometasone Furoate Cream 0.1 Percent (Pack 10gms) (Net Wt. of Mometasone Furoate Micronized 0.700 Kgs.)	70000 Numbers
12	Mometasone Furoate Cream 0.1 Percent (Pack 15gms) (Net Wt. of Mometasone Furoate Micronized 1.050 Kgs.)	70000 Numbers
13	Mometasone Furoate Cream 0.1 Percent (Pack 20gms) (Net Wt. of Mometasone	70000 Numbers

	Furoate Micronized 1.40 Kgs.)	
14	Mometasone Furoate Cream 0.1 Percent /Metactiv Cream 0.10 Percent (Pack 30gms) (Net Wt. of Mometasone Furoate Micronized 2.40 Kgs.)	80000 Numbers
15	Mometasone Furoate Cream 0.1 Percent (Pack 45gms) (Net Wt. of Mometasone Furoate Micronized 3.600 Kgs.)	80000 Numbers
16	Mometasone Furoate Cream 0.1 Percent (Pack 50gms) (Net Wt. of Mometasone Furoate Micronized 7.500 Kgs.)	150000Numbers
17	Mometasone Furoate Cream 0.1 Percent (Pack 60gms) (Net Wt. of Mometasone Furoate Micronized 17.400 Kgs.)	290000Numbers
18	Mometasone Furoate Cream 0.1 Percent (Pack 100gms) (Net Wt. of Mometasone Furoate Micronized 29.000 Kgs.)	290000Numbers

Sl. No.	Import Items	Qty. allowed
1	Mometasone Furoate Micronized	79.897 kg.

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

Case No.	184 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003135AM23
RA File Number	03AX04003158 AM23
Licence No and Date	0311017885/15/09/2022
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms for export to US only are as under:-	

S.No	Export Product	Quantity
1	Medical cream & Ointments(CICLOPIROX SOLUTION TOPICAL 8% 6.6ML Tot WT 1650 Kgs. (Net Cont :Ciclopirox 132Kgs, Isoprop 511.5 Kg, Ethyl ace 511.5Kgs, Buty est 495 Kgs, Glass bottle 250000 Nos, brush 250000 Nos, Cap ribb 250000 Nos))	1 Number

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

Note:

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

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

Case No.	185 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	KRITI NUTRIENTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003136AM23
RA File Number	56AX04000172 AM23
Licence No and Date	5611001168/15/09/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Soya Lecithin Liquid Food Grade (Non GMO)	1 MT	1	Crude Soya Lecithin Liquid	1.01 MT

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

Case No.	186 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003140AM23
RA File Number	08AX04001000 AM23
Licence No and Date	0811006039/15/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MeET/Nov/202324/16** dated 17/11/2023 against advance authorization **No.0811004766** dated 23/04/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NALTREXONE HYDROCHLORIDE TABLETS USP 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE USP 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 328.500 KGS.]	1 Number	1	NALTREXONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR	51.93 mg / tablet

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

Case No.	187 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003158AM23
RA File Number	05AX04001697 AM23
Licence No and Date	0511014860/16/09/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TESA-1-(3-CHLOROPYRIDIN-2YL)-3-[5-TRIFLUOROMETHYL)-2H-TETRAZOL-2YLMETHYL-1H-PYRAZOLE-5- CARBOXYLIC ACID(TESA-1-(3-CHLOROPYRIDIN-2YL)-3-[5-(TRIFLUOROMETHYL)-2H-TETRAZOL-2YLMETHYL-1H-PYRAZOLE-5-CARBOXYLIC ACID)	1 kg.	1	Methyl 5- (chloromethyl)-2-(3-chloro-2-pyridyl) pyrazole-3-carboxylate(comes as 33% solution in toluene)	2.90 kg.
		2	Sodium 5-(trifluoromethyl)-1,2,4-triaza-3-azanidacyclopenta-1,4-diene (comes as 28% solution in acetone)	1.91 kg.

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

Case No.	188 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003169AM23
RA File Number	03AX04003215 AM23
Licence No and Date	0311017939/16/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Nov/202324/16 dated 17/11/2023** against advance authorization **No.0511013170 dated 13/06/2022** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
OFLOXACIN OPHTHALMIC SOL 0.3% 5.0ML (OFLOXACIN EYE DROPS 5ML)((EACH VIAL CONTAINS OFLOXACIN 0.015 GM NET WT OF BULK DRUG IS 21.06 KGS))	1 Number	1	OFLOXACIN USP	15.30 mg.
OFLOXACIN OPHTHALMIC SOL 0.3% 10.0ML (OFLOXACIN EYE DROPS 10 ML)((EACH VIAL CONTAINS 2 OFLOXACIN 0.03 GM NET WT OF BULK DRUG IS 5.580 KGS))	1 Number	2	OFLOXACIN USP	30.60 mg.

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

Case No.	189 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003172AM23
RA File Number	03AX04003088 AM23
Licence No and Date	0311017943/16/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	190 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003187AM23
RA File Number	08AX04000985 AM23
Licence No and	0811006052/19/09/2022

Date

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Nov/202324/16 dated 17/11/2023** against advance authorization **No.0811004640 dated 13/04/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL] (EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	1	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	61.87 mg / vial
METHOTREXATE INJECTION BP 100MG/ML [5 ML VIAL] (EACH ML CONTAINS: METHOTREXATE PH. EUR. 100 MG)	1 Number Vial	2	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	618.70 mg / vial
METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL] (EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)	1 Number Vial	3	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1237.39 mg / vial
METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL] (EACH ML CONTAINS: METHOTREXATE USP 25MG)	1 Number Vial	4	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	306.867 mg / vial
METHOTREXATE INJECTION BP 25MG/ML [20ML VIAL] (EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	5	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	590.57 mg / vial
METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL] (EACH ML CONTAINS:	1 Number Vial	6	METHOTREXATE EP / BP / IP / USP / PH. EUR.	1181.15 mg / vial

METHOTREXATE PH. EUR. 25MG)			(Moisture and Residual Solvents content not less than 12.49% in API)	
METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL] (EACH ML CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 14.300 KGS.]	1 Number Vial	7	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	5737.00 mg / vial

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

Case No.	191 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003190AM23
RA File Number	30AX04000248 AM23
Licence No and Date	3011002599/19/09/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Injection Urokinase	1000 vials	1	Urokinase	1043.46 mg.
		2	Mannitol 0.5%	128.52 gm.
		3	Sodium Chloride (50 mg/vial)	128.52 gm.
		4	Sodium Hydroxide	3.06 gm.

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

Case No.	192 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	CANPEX CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003225AM23
RA File Number	31AX04000170 AM23
Licence No and Date	3111001703/20/09/2022
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following documents from the firm:- Complete CoA of import item from foreign supplier	

Case No.	193 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	ZYDUS LIFESCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00003228AM23			
RA File Number	08AX04000781 AM23			
Licence No and Date	0811006058/20/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
LUBIPROSTONE CAPSULES 8 MCG ((ACTIVE INGREDIENT: LUBIPROSTONE - NET WT. 148.010 GMS.))	1 Number	1	LUBIPROSTONE	8.16 mcg
		2	GELATIN NF	332.17 mg
		3	SORBITOL SORBITAN SOLUTION NF	99.49 mg
		4	PROPYLENE GLYCOL NF	2.50 mg

LUBIPROSTONE CAPSULES 24 MCG ((ACTIVE INGREDIENT: LUBIPROSTONE - NET WT. 985.036 GMS.))	Sl. Number	5	LUBIPROSTONE	24.48 mcg
		6	GELATIN NF	332.17 mg
		7	SORBITOL SORBITAN SOLUTION NF	99.45 mg
		8	PROPYLENE GLYCOL NF	2.50 mg

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

Case No.	194 / NC/3/MEET/Dec/202324/17										
Case Status	Case Approved										
Party Name	LASENOR INDIA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023										
HQ File Number	HQRNORM APPLY 00003231AM23										
RA File Number	50AX04000046 AM23										
Licence No and Date	5011000583/20/09/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Sunflower Lecithin (Powder)</td><td>1 MT</td><td>1</td><td>Crude Sunflower Lecithin Liquid</td><td>1.40 MT</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Sunflower Lecithin (Powder)	1 MT	1	Crude Sunflower Lecithin Liquid	1.40 MT
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Sunflower Lecithin (Powder)	1 MT	1	Crude Sunflower Lecithin Liquid	1.40 MT							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	195 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	BEST VALUE CHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00003244AM23			
RA File Number	34AX04000595 AM23			
Licence No and	3411002799/20/09/2022			

Date				
Norms Committee Decision:				
Dr. Dhaval Patel, Technical Expert, Shri Dhruval Parmar (Exim) of the firm had attended the Personal Hearing and explained the case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for review of ad-hoc norms on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under, or as applied whichever is less: -				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Dimethyl Benzyl Carbinyl Butyrate (1-Cyclohexyl-2-methylpropan-2-yl butanoate))	1 kg.	1	N Butyric Anhydride	0.80 kg.
		2	Magnesium Turning	0.17 kg.

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

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

Case No.	196 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003251AM23
RA File Number	34AX04000590 AM23
Licence No and Date	3411002800/21/09/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	197 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003252AM23
RA File Number	03AX04002221 AM23
Licence No and Date	0311018044/21/09/2022
Norms Committee Decision:	

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

Case No.	198 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003266AM23
RA File Number	08AX04001009 AM23
Licence No and Date	0811006072/21/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	199 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003282AM23
RA File Number	03AX04003288 AM23
Licence No and Date	0311018056/22/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/May/202223/3 dated 27/05/2022** against advance authorization **No. 0311005647 dated 27/07/2021** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Sl. No.	Export Product	Qty.
1	Desonide Cream 0.05 Percent 15gm (Net Wt. of Desonide USP is 0.375 Kgs)	1 Number
2	Desonide Cream 0.05 Percent 60gm (Net Wt. of Desonide USP is 1.500 Kgs)	1 Number
3	Desonide Lotion 0.05 Percent 59ml (Net Wt. of Desonide USP is 1.475 Kgs)	1 Number
4	Desonide Lotion 0.05 Percent 118ml (Net Wt. of Desonide USP is 2.950 Kgs)	1 Number
5	Desonide Ointment 0.05 Percent 15gm (Net Wt. of Desonide USP is 0.375 Kgs)	1 Number

6	Desonide Ointment 0.05 Percent 60gm (Net Wt. of Desonide USP is 1.050 Kgs)						1 Number
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Sl. No.	Import Items	For the Export of 1 No. Pack					
		0.05% 15gm pack	0.05% 60gm pack	0.05% 59ml pack	0.05% 118ml pack	0.05% 15gm pack	0.05% 60gm pack
1	Desonide USP Micronised (Sicor)	0.00765 gm	0.0306 gm	0.0301 gm	0.0602 gm	0.00765 gm	0.0306 gm

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

Case No.	200 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003283AM23
RA File Number	03AX04003060 AM23
Licence No and Date	0311018071/22/09/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	201 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003302AM23
RA File Number	03AX04003171 AM23
Licence No and Date	0311018082/22/09/2022
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Aug/202324/11 dated 22/08/2023 against advance	

authorization **No. 0311007542 dated 07/10/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

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

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

Case No.	202 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006256AM24
RA File Number	08AX04000971 AM23
Licence No and Date	0811006083/22/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	203 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	HONOUR LAB LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00003320AM23			
RA File Number	09AX04000492 AM23			
Licence No and Date	0911003685/23/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DAPAGLIFLOZIN	1 kg.	1	(2R,3R,4R,5S,6S)-2-(Acetoxymethyl)-6-(4-chloro-3-(4-ethoxybenzyl)phenyl)tetrahydro-2H-pyran-3,4,5-triyl triacetate	1.428 kg.
		2	(S)-(+)-1,2-propanediol	0.190 kg.

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

Case No.	204 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	KAVALIFE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003326AM23
RA File Number	07AX04000884 AM23
Licence No and Date	0711005312/23/09/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Complete CoA of import item from foreign supplier indicating moisture content and caffeine content.	

Case No.	205 / NC/3/MEET/Dec/202324/17													
Case Status	Case Approved													
Party Name	AROHEMA INGREDIENTS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023													
HQ File Number	HQRNORM REVIW00006494AM24													
RA File Number	26AX04000054 AM23													
Licence No and Date	2611000716/23/09/2022													
Norms Committee Decision:														
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under.														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">ORCANOX</td><td rowspan="2">1 kg.</td><td>1</td><td>SCLAREOL</td><td>2.0458 kg.</td></tr><tr><td>2</td><td>TERT - AMYL ALCOHOL</td><td>2.64 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ORCANOX	1 kg.	1	SCLAREOL	2.0458 kg.	2	TERT - AMYL ALCOHOL	2.64 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
ORCANOX	1 kg.	1	SCLAREOL	2.0458 kg.										
		2	TERT - AMYL ALCOHOL	2.64 kg.										
Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by														

RA on above norms.

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

Case No.	206 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003339AM23
RA File Number	03AX04003267 AM23
Licence No and Date	0311018114/24/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	207 / NC/3/MEET/Dec/202324/17		
Case Status	Case Approved		
Party Name	ENCUBE ETHICALS PRIVATE LIMITED		
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023		
HQ File Number	HQRNORM APPLY 00003351AM23		
RA File Number	03AX04003157 AM23		
Licence No and Date	0311018125/24/09/2022		
Norms Committee Decision:			
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms for export to US only are as under:-			

1	Relevant Bulk Drugs	Net content in the export product plus 3% wastage.
2	Relevant Excipients	Net content in the export product plus 3% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy

Note:

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

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

Case No.	208 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003352AM23
RA File Number	03AX04003159 AM23
Licence No and Date	0311018126/24/09/2022

Norms Committee Decision:

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

S.No	Export Product	Quantity
1	Medical Creams & Ointments(ADAPALENE GEL 0.3% 45GM Tube Wt: 6225.03 Kgs (Net Number Cont: Adapal8.4 Kgs, Edetate2.8Kgs, Poloxamer5.6Kgs, Carbomer30.81 Kgs, Methy5.6 Kgs, Propel112.05Kgs, sodium Hy 7Kgs,Hydrocl 14.01Kgs,Tubes138334Nos))	

2	Medical Creams & Ointments(ADAPALENE GEL 0.3% 45GM Pump Wt: 6000.03 Kgs (Net Cont: Adapal8.1Kgs, Edetate 2.7Kgs, Poloxamer 5.4Kgs, Carbomer 29.7Kgs, Methyl 5.4Kgs, Propel 108Kgs, sodium Hy 6.75Kgs, Hydrocl 13.5 Kgs,Pump body 133334Nos Pump Engine 133334Nos))	1 Number
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S.No	Import Product	Quantity
1	Relevant Bulk Drugs	Net content in the export product plus 3% wastage.
2	Relevant Excipients	Net content in the export product plus 3% wastage.
3	Relevant Packaging Material	Relevant as per Packing Policy

Note:

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

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

Case No.	209 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003361AM23
RA File Number	03AX04003290 AM23
Licence No and Date	0311018149/25/09/2022
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms for export to US only are as under:-	

S.No	Export Product	Quantity
1	Medicals Creams & Ointments(Triamcinolone Acetonide Ointment USP, 0.05% 430gm Tot Wt: 150500 Kgs (Net Cont: Triamcinolone 32.35Kgs, Lanolin 1941.10Kgs, Oil 2588.13Kgs, White Petrolatum 22613.82Kgs, Jara 350000Nos, Caps 350000Nos))	1 Number

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

Note:

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

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

Case No.	210 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003366AM23
RA File Number	03AX04003250 AM23

Licence No and Date	0311018155/25/09/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- Get the Advance Authorisation amended to show content of API in export in line with DML.	

Case No.	211 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003389AM23
RA File Number	08AX04001054 AM23
Licence No and Date	0811006114/26/09/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	212 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003395AM23
RA File Number	34AX04000620 AM23
Licence No and Date	3411002830/27/09/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	213 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003409AM23
RA File Number	07AX04000935 AM23
Licence No and Date	0711005338/27/09/2022
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Direct Compression Granules of Phloroglucinol 160 mg ODT PREMIX ((Each 450mg of Premix Contains Phloroglucinol 160mg = 160 Kg)	1 kg.	1	PHLOROGLUCINOL DIHYDRATE PH.EUR	0.359 kg.

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

Case No.	214 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003417AM23
RA File Number	09AX04000478 AM23
Licence No and Date	0911003707/27/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	215 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	GUJARAT FLUOROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003434AM23
RA File Number	34AX04000334 AM23
Licence No and Date	3411002838/28/09/2022
Norms Committee Decision:	
The committee considered the request of firm for review of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
I. Step wise manufacturing process. II. Complete chemical reactions with molecular and structural formula and molecular weights along with	

stage wise percentage yields on molar basis.

III. Complete technical details as per Annexure to Appendix 4E for chemical products.

IV. Stoichiometric balance between import and export on molar basis.

V. Details of indigenous input with quantity.

VI. Sample of shipping bills and bill of entry of the export products along with statement of Input-output as per export documents of the said authorization.

Case No.	216 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003479AM23
RA File Number	08AX04000835 AM23
Licence No and Date	0811006153/30/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	217 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	ALCHEMIE FINECHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00003491AM23			
RA File Number	03AX04002329 AM23			
Licence No and Date	0311018301/30/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/May/202324/4 dated 26/05/2023 against advance authorization No.0311020946 dated 24/01/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty.
N, ETHYL N,BENZYL ANILINE SULPHONIC ACID(N,ETHYL-N-(3SULFOBENZYL) ANILINE	1 Kg.	1	ANILINE	0.40 Kg.
		2	BENZYL CHLORIDE	0.54 Kg.
		3	CAUSTIC SODA LYE	0.344 Kg.

		4	DENATURED ETHYL ALCOHOL	0.198 Kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	218 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003514AM23
RA File Number	03AX04003421 AM23
Licence No and Date	0311018336/03/10/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Step wise percentage yield on molar basis at each step of reaction. 2. Commercial value of each by-product obtained with documentary evidence.	

Case No.	219 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003540AM23
RA File Number	03AX04003155 AM23
Licence No and Date	0311018363/05/10/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	220 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	GEM AROMATICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003541AM23
RA File Number	03AX04003363 AM23
Licence No and	0311018364/05/10/2022

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CIS-3-HEXENYL ACETATE (Containing Net Content of Import Item: 1923.077 Kgs. excluding wastage)	1 kg.	1	CIS 3 Hexenol Natural (Leaf Alcohol)	0.7417 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	221 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	CORAL DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003543AM23
RA File Number	05AX04001818 AM23
Licence No and Date	0511015160/06/10/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	222 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	ASTEC LIFESCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00003551AM23			
RA File Number	03AX04003473 AM23			
Licence No and Date	0311018382/06/10/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

PDSH(3-(4-CHLORO-2-FLUORO-5-MERCAPTO-PHENYL)-1-METHYL-6-TRIFLOUOROMETHYL-1H-PYRIMIDINE-2,4-DIONE TECHNICAL (PDSH))	1 kg.	1	2 FLUORO ANILINE	0.66 kg.
		2	ETHYL CHLOROFORMATE	0.55 kg.
		3	DIMETHYL FORMAMIDE	Deleted (not given in production/consumption data & also not a main reactant
		4	ETHYL 3 AMINO 4 4 4 TRIFLUOROCROTONATE	0.66 kg.
		5	POTASSIUM CARBONATE	0.31 kg.

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

Case No.	223 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003555AM23
RA File Number	52AX04001659 AM23
Licence No and Date	5211003386/06/10/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	224 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003598AM23
RA File Number	03AX04003430 AM23
Licence No and Date	0311018444/09/10/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BENZYL BENZOATE	1 kg.	1	BENZOIC ACID	0.639 kg.
		2	BENZYL ALCOHOL	0.566 kg.

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

Case No.	225 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003610AM23
RA File Number	34AX04000652 AM23
Licence No and Date	3411002874/10/10/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	226 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ENCEE AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003616AM23
RA File Number	32AX04000290 AM23
Licence No and Date	3211003763/11/10/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	227 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003617AM23
RA File Number	03AX04003479 AM23
Licence No and	0311018489/11/10/2022

Date

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No.0311023165 dated 27/04/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
CEFOTAXIME SODIUM STERILE USP / BP	1 kg.	1	CEFOTAXIME ACID NON STERILE	0.989 kg.

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

Case No.	228 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	LIVEALTH BIOPHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003619AM23
RA File Number	03AX04003335 AM23
Licence No and Date	0311018491/11/10/2022
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	229 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003624AM23
RA File Number	04AX04000581 AM23
Licence No and Date	0411004084/11/10/2022
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202223/24 dated 13/04/2023 against advance authorization No.0411003383 dated 26/05/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty.
IBUPROFEN USP	1 Kg.	1	Isobutyl Acetophenone	1.110 kg
		2	Sodium Metal	0.235 kg
		3	Monochloro Acetic Acid	0.919 kg
		4	Iso Propyl Alcohol	0.500 kg
		5	Sodium Dichromate	0.630 kg

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

Case No.	230 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003625AM23
RA File Number	04AX04000582 AM23
Licence No and Date	0411004085/11/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202223/24 dated 13/04/2023** against advance authorization **No.0411003383 dated 26/05/2022**; it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
IBUPROFEN USP	1 Kg.	1	Isobutyl Acetophenone	1.110 kg
		2	Sodium Metal	0.235 kg

		3	Monochloro Acetic Acid	0.919 kg
		4	Iso Propyl Alcohol	0.500 kg
		5	Sodium Dichromate	0.630 kg

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

Case No.	231 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003629AM23
RA File Number	34AX04000662 AM23
Licence No and Date	3411002884/11/10/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	232 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003643AM23
RA File Number	09AX04000594 AM23
Licence No and Date	0911003780/11/10/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	233 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003648AM23
RA File Number	05AX04001858 AM23
Licence No and	0511015244/11/10/2022

Date

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Oct/202324/15** dated **13/10/2023** against advance authorization **No. 0510413850 dated 12/03/2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Buprenorphine Hydrochloride (Bulk Drug/ Pharmacopeal Grade)	1 kg.	1	7(Alpha)-(2-Hydroxy-3,3-Dimethyl-2-Butyl)-6, 14-Endo-Ethano-6, 7, 8, 14-Tetrahydronorthebaine	1.955 kg.
		2	Cyclopropyl methanol	1.60 kg.
		3	Mehtane Sulfonyl Chloride	2.50 kg.
		4	Lithium Bromide	2.00 kg.
		5	Thiophenol	2.50 kg.
		6	Dimethyl Formamide	4.00 kg.
		7	Triethyl Amine	4.80 kg.
		8	Toluene	20.50 kg.
		9	Methanol	5.50 kg.
		10	Activated Carbon / Eno Carbon	0.200 kg.
		11	Acetone	4.50 kg.

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

Case No.	234 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023

and Date	
HQ File Number	HQRNORM APPLY 00003663AM23
RA File Number	09AX04000574 AM23
Licence No and Date	0911003782/12/10/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	235 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003691AM23
RA File Number	09AX04000567 AM23
Licence No and Date	0911003791/13/10/2022
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
Commercial value of by-product obtained with documentary evidence.	

Case No.	236 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	VINS BIOPRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003701AM23
RA File Number	09AX04000630 AM23
Licence No and Date	0911003795/13/10/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	237 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003713AM23

RA File Number	09AX04000603 AM23			
Licence No and Date	0911003803/14/10/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
5-Hydroxy-1,3-oxathiolane-2-carboxylicacid (1R,2S,5R) menthyl ester(5-Hydroxy-1,3-oxathiolane-2-carboxylicacid(1R,2S,5R) menthyl ester)	1 kg.	1	Glyoxylic acid 50 %	0.69 kg.
		2	Sodium bisulphite	0.55 kg.
		3	2,5-dihydroxy-1,4-dithiane	0.28 kg.
		4	Formaldehyde	0.46 kg.
		5	N-Hexane	0.44 kg.
		6	Toluene	0.22 kg.
		7	Cyclohexane	0.55 kg.
		8	L-(-) Menthol 99%	0.725 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	238 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003742AM23
RA File Number	05AX04001751 AM23
Licence No and Date	0511015334/14/10/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Mar/202223/24 dated 13/04/2023** against advance authorization **No.0510413373 dated 17/01/2020** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed (in Kg.)
Naltrexone Hydrochloride (Bulk Drug/ Pharmacopeial Grade)	1 kg.	1	Noroxymorphone	1.20
		2	5% palladium carbon(50% wet)	Not required in relevant process steps.
		3	Cyclopropyl methanol	1.35
		4	Methane Sulfonyl Chloride	2.00
		5	Lithium Bromide	1.65
		6	Hydrochloric Acid	Not importable item
		7	Acetic Acid	Not required in relevant process steps.
		8	Ammonia Liquor	Not required in relevant process steps.
		9	Dimethyl Formamide	2.57
		10	Cyclohexene	3.60
		11	Ethyl Acetate	8.00
		12	Triethyl Amine	3.77
		13	Eno carbon / Activated Carbon	0.100

For **export item no.2**, it was decided to ratify ad-hoc norms as per **SION A-412**.

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

Case No.	239 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	ORIENTAL AROMATICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003761AM23
RA File Number	03AX04003660 AM23
Licence No and Date	0311018607/17/10/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Exact use of Acetic Acid in the production process. 2. Production/Consumption data duly certified by GST for last two years.	

Case No.	240 / NC/3/MEET/Dec/202324/17	
Case Status	Case Approved	
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023	
HQ File Number	HQRNORM APPLY 00003783AM23	
RA File Number	03AX04003611 AM23	
Licence No and Date	0311018641/17/10/2022	
Norms Committee Decision:		
Shri Kunal Sikchi, Director and Shri Nitin Vyas, Sr. Executive of the firm had attended the Personal Hearing and explained firm’s case. The Committee heard the explanation of Representative of the firm and after due deliberation the committee has considered for fixation of ad-hoc norms as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Oct/202122/9 dated 15/10/2021 against advance authorization No. 0310837496dated 30/07/2020, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-		
Sl. No.	Export Product	Qty.
1	Phytosterol Natural Refined Phytosterol 95%	1,20,000.0 kg.

2	Natural Mixed Tocopherol 50%	77000.0 kg.
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Sl. No.	Import Item	Qty.
1	Fatty Acid Distillate / Deoderised Distillate	18, 42,500 kg.
2	Acetone	88,000 kg.
3	N-HEPTANE	1,88,100 kg.

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

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

Case No.	241 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	MEDREICH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003824AM23
RA File Number	07AX04001015 AM23
Licence No and Date	0711005482/19/10/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	242 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003867AM23
RA File Number	07AX04001068 AM23
Licence No and Date	0711005519/21/10/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Lisinopril 2.5 Mg Tablets(Lisinopril Tablets 2.5 Mg (7.5 kg))	1 Number	1	Lisinopril Dihydrate Ph. Eur.	2.55 mg / tablet
Lisinopril 5 Mg Tablets(Lisinopril Tablets 5 Mg (15.00 kg))	1 Number	2	Lisinopril Dihydrate Ph. Eur.	5.10 mg / tablet
Lisinopril 5 Mg+Amlodipine 5mg Tablets((14 kg))	1 Number	3	Lisinopril Dihydrate Ph. Eur.	5.10 mg / tablet
		4	Amlodipine Besilate BP	5.10 mg / tablet
Lisinopril 10 Mg+Amlodipine 5mg Tablets((44.55 kg))	1 Number	5	Lisinopril Dihydrate Ph. Eur.	10.2 mg / tablet
		6	Amlodipine Besilate BP	5.10 mg / tablet

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

Case No.	243 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003896AM23
RA File Number	07AX04001078 AM23
Licence No and Date	0711005538/21/10/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Nifuroxazide	1 kg.	1	5-Nitro-2-furohydrazide	0.634 kg.

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

Case No.	244 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003897AM23
RA File Number	07AX04001077 AM23
Licence No and Date	0711005539/21/10/2022

Norms Committee Decision:

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

1. To give Chemistry of the reaction indicating molecular weight of both reactant and product and calculation.
2. Yield of the reaction with justification and also end uses of the export item.
3. Copy of norms, if the same is fixed in the past.

Case No.	245 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003899AM23
RA File Number	07AX04001086 AM23
Licence No and Date	0711005541/21/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Dec/202223/15 dated 29/12/2022** against advance authorization **No.0711004736 dated 21/07/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	MAGNESIUM ASCORBATE	1 kg	1	ASCORBIC ACID - ANY GRADE	1.1 kg
2	CALCIUM ASCORBATE (BP/USP)	1 kg	1	ASCORBIC ACID - ANY GRADE	0.964 kg

3	ZINC ASCORBATE	1 kg	1	ASCORBIC ACID - ANY GRADE	0.989 kg
4	SODIUM ASCORBATE (BP/EP/USP)	1 kg	1	ASCORBIC ACID - ANY GRADE	1.03 kg

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

Case No.	246 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003914AM23
RA File Number	08AX04001242 AM23
Licence No and Date	0811006339/25/10/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Sep/202324/14 dated 27/09/2023** against advance authorization **No.0811009097 dated 16/08/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
ISOSORBIDE MONONITRATE EXTENDED RELEASE TABLETS USP 60 MG EACH FILM COATED EXTENDED RELEASE TABLETS(CONTAINS: DILUTED ISMN (50% DILUTED WITH LACTOSE MONOHYDRATE) USP EQUIVALENT TO ISOSORBIDE MONONITRATE 60MG, NET CONTENT OF ACTIVE INGREDIENT ISOSORBIDE MONONITRATE SHOULD NOT BE LESS THAN 1980.000 KGS.)	1 Number	1	Isosorbide Mononitrate 50 percent Assay. Diluted ISMN (50% diluted with lactose monohydrate) USP	122.40 mg
ISOSORBIDE MONONITRATE EXTENDED RELEASE TABLETS USP 120 MG EACH FILM COATED	1 Number	2	Isosorbide Mononitrate 50 percent Assay. Diluted ISMN (50% diluted with lactose	244.80 mg

EXTENDED RELEASE TABLETS(CONTAINS: DILUTED ISMN (50% DILUTED WITH LACTOSE MONOHYDRATE) USP EQUIVALENT TO ISOSORBIDE MONONITRATE 120MG, NET CONTENT OF ACTIVE INGREDIENT ISOSORBIDE MONONITRATE SHOULD NOT BE LESS THAN 1320.000 KGS.)			monohydrate) USP	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	247 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003925AM23
RA File Number	09AX04000647 AM23
Licence No and Date	0911003881/27/10/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	248 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00003948AM23			
RA File Number	07AX04001102 AM23			
Licence No and Date	0711005565/28/10/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No.0711004103 dated 26/05/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

PHLOROGLUCINOL VIATRIS 160mg ODT (560 KG)	1 Number	1	PHLOROGLUCINOL DIHYDRATE PH EUR	163.20 mg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	249 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	NECTAR LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00003987AM23
RA File Number	302404000100 AM20
Licence No and Date	3011002766/01/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	250 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	BRAWN LABORATORIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00003991AM23			
RA File Number	05AX04001882 AM23			
Licence No and Date	0511015547/01/11/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Amikacin Sulphate Injection 100mg - 2ML(Clear colourless to pale yellow solution filled in clear glass sealed vials.)	1 Number	1	Amikacin Sulphate	715.81 mg
Amikacin Sulphate Injection 500mg - 2ML(Clear colourless to pale yellow solution filled in clear glass sealed vials.)	1 Number	2	Amikacin Sulphate	143.16 mg

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

Case No.	251 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00004014AM23
RA File Number	05AX04002182 AM23
Licence No and Date	0511015566/01/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	252 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00004025AM23			
RA File Number	04AX04000654 AM23			
Licence No and Date	0411004350/02/11/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202223/24 dated 13/04/2023 against advance authorization No.0411003383 dated 26/05/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty.
IBUPROFEN USP	1 Kg.	1	Isobutyl Acetophenone	1.110 kg
		2	Sodium Metal	0.235 kg
		3	Monochloro Acetic Acid	0.919 kg
		4	Iso Propyl Alcohol	0.500 kg

		5	Sodium Dichromate	0.630 kg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	253 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SHIVA BIO CHEM INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00004047AM23
RA File Number	50AX04000064 AM23
Licence No and Date	5011000667/03/11/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sunflower Lecithin (Liquid)	1 MT	1	Crude Sunflower Lecithin	1.01 MT

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

Case No.	254 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	VASISTA LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00004049AM23
RA File Number	09AX04000675 AM23
Licence No and Date	0911003903/03/11/2022

Norms Committee Decision:

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

Case No.	255 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00004071AM23
RA File Number	09AX04000645 AM23
Licence No and Date	0911003906/04/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	256 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	AMARA LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00004072AM23
RA File Number	09AX04000646 AM23
Licence No and Date	0911003907/04/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	257 / NC/3/MEET/Dec/202324/17			
Case Status	Case Approved			
Party Name	INTAS PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023			
HQ File Number	HQRNORM APPLY 00004123AM23			
RA File Number	08AX04001251 AM23			
Licence No and Date	0811006379/07/11/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Nov/202324/16 dated 17/11/2023 against advance authorization No.0811002393 dated 25/08/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
VINORELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 1ML VIAL (EACH ML CONTAINS: VINORELBINE	1 Number	1	VINORELBINE TARTRATE EP / BP / IP / USP / PH. EUR	14.33 mg.

TARTRATE PH.EUR EQ. TO VINOELBINE 10 MG)			(Water content 2.3%)	
VINOELBINE CONCENTRATE FOR SOLUTION FOR INFUSION 10MG/ML, 5ML VIAL (EACH ML CONTAINS: VINOELBINE TARTRATE PH.EUR EQ. TO VINOELBINE 10 MG [IN WHICH ACTIVE INGREDIENT VINOELBINE TARTRATE USED IS 967.000 GRAMS])	1 Number	2	VINOELBINE TARTRATE EP / BP / IP / USP / PH. EUR (Water content 2.3%)	71.66 mg.

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

Case No.	258 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00004212AM23
RA File Number	05AX04002149 AM23
Licence No and Date	0511015679/09/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	259 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	VACHICHEM INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00004219AM23
RA File Number	07AX04001122 AM23
Licence No and Date	0711005637/09/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	260 / NC/3/MEET/Dec/202324/17
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Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006136AM24
RA File Number	52AX04001711 AM23
Licence No and Date	5211003710/07/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	261 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006412AM24
RA File Number	09AX04000649 AM23
Licence No and Date	0911004131/08/12/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	262 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	ZENITH DYEINTERMEDIATES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00005839AM24
RA File Number	03AX04004689 AM23
Licence No and Date	0311020392/02/01/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it has been observed that a Corrigendum in this regard had already been issued on 04/10/2023 and uploaded on DGFT website under Meeting No.NC/3/MEET/Aug/202324/11(Corrigendum) dated 22/08/2023 .	

Case No.	263 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	AROHEMA INGREDIENTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006495AM24

RA File Number	26AX04000089 AM23			
Licence No and Date	2611000839/08/02/2023			
Norms Committee Decision:				
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under.				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ORCANOX	1 kg.	1	SCLAREOL	2.0458 kg.
		2	TERT - AMYL ALCOHOL	2.64 kg.
Note: The above norms are for regularization and closure purpose only. No repeat Licence may be allowed by RA on above norms.				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	264 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006482AM24
RA File Number	08AX04001877 AM23
Licence No and Date	0811007279/10/02/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith relevant documents.	

Case No.	265 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006483AM24
RA File Number	08AX04002002 AM23
Licence No and Date	0811007388/27/02/2023

Norms Committee Decision:

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

Case No.	266 / NC/3/MEET/Dec/202324/17
Case Status	Case Rejected
Party Name	FOURRTS (INDIA) LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006325AM24
RA File Number	04AX04000012 AM24
Licence No and Date	0411005247/17/04/2023

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to **reject** the case maintaining the **status quo**.

Case No.	267 / NC/3/MEET/Dec/202324/17
Case Status	Case Rejected
Party Name	FOURRTS (INDIA) LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006324AM24
RA File Number	04AX04000046 AM24
Licence No and Date	0411005256/18/04/2023

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to **reject** the case maintaining the **status quo**.

Case No.	268 / NC/3/MEET/Dec/202324/17
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006125AM24
RA File Number	08AX04000579 AM24
Licence No and Date	0811008604/05/07/2023

Norms Committee Decision:

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

Case No.	269 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	REYAANSH HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM REVIW00006424AM24
RA File Number	03AX04002203 AM24
Licence No and Date	0311026394/17/08/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SELAMECTIN 6% SPOT ON 0.25 ML TUBE (Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed Including Wastages & Overages : 1.500 Kg.)	90912 Number	1	SELAMECTIN (P.C.9 Case)	1.391 kg.
SELAMECTIN 6% SPOT ON 0.50 ML TUBE (Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed Including Wastages & Overages : 6.000 Kg.)	181836 Number	2	SELAMECTIN (P.C.9 Case)	5.564 kg.
SELAMECTIN 6% SPOT ON 0.75 ML TUBE (Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed Including Wastages & Overages : 11.200 Kg)	226278 Number	3	SELAMECTIN (P.C.9 Case)	10.386 kg.
SELAMECTIN 6% SPOT ON 1 ML TUBE (Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed Including Wastages & Overages : 7.200 Kg)	109096 Number	4	SELAMECTIN (P.C.9 Case)	6.677 kg.
SELAMECTIN 6% SPOT ON 2 ML TUBE (Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed	69699 Number	5	SELAMECTIN (P.C.9 Case)	8.531 kg.

Including Wastages & Overages : 9.200 Kg)				
SELAMECTIN 6% SPOT ON 4 ML TUBE(Each ml Contains Selamectin 60 mg Net Quantity of Selamectin Consumed Including Wastages & Overages : 5.600 Kg)	21213 Number	6	SELAMECTIN (P.C.9 Case)	5.193 kg.

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

Case No.	270 / NC/3/MEET/Dec/202324/17
Case Status	Case Approved
Party Name	SUPRIYA LIFESCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Dec/ 202324/ 17 and 20/12/2023
HQ File Number	HQRNORM APPLY 00006357AM24
RA File Number	03AX04003085 AM24
Licence No and Date	0311028054/19/10/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
RIBOFLAVIN SODIUM PHOSPHATE HYDRATE EP 11.2	1 kg.	1	RIBOFLAVIN (Vitamine B2)	1.10 kg.
		2	PYRIDINE	2.00 kg.
		3	ACETONITRILE	1.73 kg.
		4	PHOSPHORUS OXYCHLORIDE	2.00 kg.

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