



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

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/Sep/202425/9

DATED: 10/10/2024

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.
- IV. RAs shall ensure compliance of SION, General Notes and Chapter Notes wherever applicable.
- V. RAs shall also ensure that authorisation is issued or redeemed based on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less. In this regard full compliance of the provisions of Para 4.12 of FTP, Para 4.16, Para 4.21 and Para 4.51 of HBP shall be made.

Meeting No. NC/3/MEET/Sep/202425/9 dated 10/10/2024 of Norms Committee - III for the year 2024-25 was held on 10/10/2024 under the Chairmanship of Shri Rakesh Kumar, Additional DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2023.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	Shri Rakesh Kumar, Addl. DGFT	DGFT(HQ)

2	Shri Raman Kumar, Deputy DGFT	DGFT(HQ)
3	Shri Dinesh Narain Mathur, Technical Expert	Consultant (Pharma)
4	Shri Shaish Kumar, Technical Expert	Consultant (Chemical)
5	Shri Nand Lal, Technical Expert	Consultant (Chemical)
6	Shri Uttam Dey Sarkar, ASO	DGFT (HQ)

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Sep/202425/9										
Case Status	Case Approved										
Party Name	AMOLI ORGANICS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024										
HQ File Number	HQRNORM REVIW00009045AM24										
RA File Number	039404000337 AM12										
Licence No and Date	0310646104/03/08/2011										
Norms Committee Decision:											
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>Levetiracetam Micronized (Not less than 90% pass through 40 mesh)</td><td>1 kg.</td><td>1</td><td>Levetiracetam</td><td>1.00 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Levetiracetam Micronized (Not less than 90% pass through 40 mesh)	1 kg.	1	Levetiracetam	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Levetiracetam Micronized (Not less than 90% pass through 40 mesh)	1 kg.	1	Levetiracetam	1.00 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	2 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00009259AM24
RA File Number	039504000262 AM13
Licence No and Date	0310705888/22/08/2012
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Justification of low yield i.e. 52.01% to 58.9% with published literature, if any. 2. Percentage losses in purification stage. 3. Certified copy of Production/Consumption data.	

Case No.	3 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00000261AM24
RA File Number	039404000617 AM17
Licence No and Date	0310808312/06/10/2016
Norms Committee Decision: 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 along with relevant documents.	

Case No.	4 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00000263AM24
RA File Number	039404001181 AM17
Licence No and Date	0310812323/03/04/2017
Norms Committee Decision: 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 along with relevant documents.	

Case No.	5 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00000262AM24
RA File Number	039404000295 AM18
Licence No and	0310814908/31/07/2017

Date	
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant documents.	

Case No.	6 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00000265AM24
RA File Number	039404000822 AM18
Licence No and Date	0310818765/30/01/2018
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant documents.	

Case No.	7 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	SHREE BANKEY BEHARI LAL FLAVORS
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00006890AM24
RA File Number	052404000067 AM19
Licence No and Date	0510406412/10/05/2018
Norms Committee Decision:	
Decision: The case is under consideration and CLA, Delhi was requested vide DGFT (HQ) letter No. 01/82/0007/AM-25/DES-III/31 dated 11/06/2024 to audit firm and submit production/consumption data for the year 2018-19 as sought by TE within fifteen days of receipt of said letter, however, no such response received from CLA, Delhi even after repeated reminders. Therefore, it was decided to send a D.O. letter to ADG, CLA, New Delhi in this regard.	

Case No.	8 / NC/3/MEET/Sep/202425/9													
Case Status	Case Approved													
Party Name	CROPNOSYS (INDIA) PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM REVIW00001803AM25													
RA File Number	039404000527 AM19													
Licence No and Date	0310823957/24/09/2018													
Norms Committee Decision:														
Decision: The Committee considered the case as per agenda and it was decided to revise 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>2-Amino-3-Chloro-5-Trifluoromethyl Pyridine Minimum 98% [F1]</td><td>1 kg.</td><td>1</td><td>2,3-Dichloro-5-trifluoromethyl Pyridine [DCTF]</td><td>1.20 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	2-Amino-3-Chloro-5-Trifluoromethyl Pyridine Minimum 98% [F1]	1 kg.	1	2,3-Dichloro-5-trifluoromethyl Pyridine [DCTF]	1.20 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
2-Amino-3-Chloro-5-Trifluoromethyl Pyridine Minimum 98% [F1]	1 kg.	1	2,3-Dichloro-5-trifluoromethyl Pyridine [DCTF]	1.20 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	9 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00007594AM24
RA File Number	039404001019 AM19
Licence No and Date	0310827414/01/03/2019
Norms Committee Decision:	
Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant documents.	

Case No.	10 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	VDH ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00008896AM24
RA File Number	052404000721 AM19
Licence No and Date	0510410010/20/03/2019

Norms Committee Decision:

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.
MENTHONE	1 kg.	1	META - CRESOL	0.9098 kg.
		2	ISO PROPYL ALCOHOL	1.000 kg.

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

Case No.	11 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	CONCORD BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00008666AM24
RA File Number	082404000101 AM20
Licence No and Date	0810145581/27/06/2019

Norms Committee Decision:

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.	Import Items	Qty.
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		No.		allowed.
Everolimus (Powder Foam)	5 kg.	1	(3S,6R,7E,9R,10R,14S,15E,17E,19E,21S,23S,26R,27R,34aS)- 9, 10, 12, 13, 14, 21, 22, 23, 24, 25, 26,27,32,33,34,34 a- Hexadecahydro	50.0 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	12 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00008637AM24
RA File Number	039404000497 AM20
Licence No and Date	0310831894/27/09/2019
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	13 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00008636AM24
RA File Number	039404000496 AM20
Licence No and Date	0310831890/27/09/2019
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	14 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00000048AM25
RA File Number	318304000087 AM20
Licence No and Date	3110067548/30/09/2019
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Difference in two types of export item DONOVA-BP838 and DONOVA-BP818 with its chemical names and end use. 2. Calculation of requirement of import items for both types of export item separately with justification of different norms.	

Case No.	15 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00009300AM24
RA File Number	052404000670 AM20
Licence No and Date	0510413367/17/01/2020
Norms Committee Decision: Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Quantity and value of By-product “Dipentene”	

Case No.	16 / NC/3/MEET/Sep/202425/9
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Case Status	Case Deferred
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00009301AM24
RA File Number	052404000729 AM20
Licence No and Date	0510413656/19/02/2020
Norms Committee Decision: Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Quantity and value of By-product “Dipentene”	

Case No.	17 / NC/3/MEET/Sep/202425/9															
Case Status	Case Approved															
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024															
HQ File Number	HQRNORM REVIW00005893AM24															
RA File Number	039504000017 AM21															
Licence No and Date	0310835789/21/04/2020															
Norms Committee Decision:																
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>MPL15723-DICYCLOVERINE HYDROCHLORIDE-20 MG TABLETS</td><td>1 Number</td><td>1</td><td>DICYCLOMINE HCL</td><td>20.40 mg.</td></tr><tr><td>MPL15716-DICYCLOVERINE HYDROCHLORIDE-10 MG TABLETS</td><td>1 Number</td><td>2</td><td>DICYCLOMINE HCL</td><td>10.20 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MPL15723-DICYCLOVERINE HYDROCHLORIDE-20 MG TABLETS	1 Number	1	DICYCLOMINE HCL	20.40 mg.	MPL15716-DICYCLOVERINE HYDROCHLORIDE-10 MG TABLETS	1 Number	2	DICYCLOMINE HCL	10.20 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
MPL15723-DICYCLOVERINE HYDROCHLORIDE-20 MG TABLETS	1 Number	1	DICYCLOMINE HCL	20.40 mg.												
MPL15716-DICYCLOVERINE HYDROCHLORIDE-10 MG TABLETS	1 Number	2	DICYCLOMINE HCL	10.20 mg.												

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

Case No.	18 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00009299AM24
RA File Number	052404000071 AM21
Licence No and Date	0510414288/29/05/2020
Norms Committee Decision: Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Quantity and value of By-product “Dipentene”	

Case No.	19 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00000095AM24
RA File Number	522404000013 AM21
Licence No and Date	5210043424/08/06/2020
Norms Committee Decision: 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 along with relevant documents from the firm:	

Case No.	20 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved

Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024			
HQ File Number	HQRNORM REVIW00005894AM24			
RA File Number	039504000137 AM21			
Licence No and Date	0310836741/18/06/2020			
Norms Committee Decision:				
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.
MPL56212-CLINDAMYCIN 150MG HARD CAPSULES	1 Number	1	CLINDAMYCIN HYDROCHLORIDE- RA000907	176.21 mg.
MPL56213-CLINDAMYCIN 150MG HARD CAPSULES	1 Number	2	CLINDAMYCIN HYDROCHLORIDE- RA000907	176.21 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	21 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	KOSHA CHEMTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00000014AM25
RA File Number	039404000306 AM21
Licence No and Date	0310837580/10/08/2020
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	22 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00004138AM23
RA File Number	092404000365 AM21
Licence No and Date	0910069368/22/10/2020
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	23 / NC/3/MEET/Sep/202425/9										
Case Status	Case Approved										
Party Name	MAC-CHEM PRODUCTS (INDIA) PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024										
HQ File Number	HQRNORM REVIW00005491AM24										
RA File Number	NA										
Licence No and Date	0311000185/17/12/2020										
Norms Committee Decision:											
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>Methyl Prednisolone Sodium Succinate for Injection (Lyophilised sterile Bulk)</td><td>1 kg.</td><td>1</td><td>6a-Methyl-11b,17a-dihydroxy-1,4-pregnadiene-3,20-dione</td><td>1.00 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	Methyl Prednisolone Sodium Succinate for Injection (Lyophilised sterile Bulk)	1 kg.	1	6a-Methyl-11b,17a-dihydroxy-1,4-pregnadiene-3,20-dione	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed							
Methyl Prednisolone Sodium Succinate for Injection (Lyophilised sterile Bulk)	1 kg.	1	6a-Methyl-11b,17a-dihydroxy-1,4-pregnadiene-3,20-dione	1.00 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	24 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00000254AM24
RA File Number	03AA04011698 AM21
Licence No and Date	0311000235/21/12/2020
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant documents from the firm:	

Case No.	25 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00008364AM24
RA File Number	05AA04025954 AM21
Licence No and Date	0511001043/02/02/2021
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was observed that the firm has not given the relevant details of both export items, therefore, it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents :- 1. Drug Manufacturing Licence (DML) 2. Master-Batch Formula. 3. Certificate of Analysis (CoA) of import item.	

Case No.	26 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	MAHIMA LIFESCIENCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM REVIW00000099AM25													
RA File Number	05AA04029372 AM21													
Licence No and Date	0511001191/09/02/2021													
Norms Committee Decision:														
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 border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>PREDNISOLONE MICRONISED</td> <td>190 kg.</td> <td>1</td> <td>PREDNISOLONE</td> <td>190 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PREDNISOLONE MICRONISED	190 kg.	1	PREDNISOLONE	190 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
PREDNISOLONE MICRONISED	190 kg.	1	PREDNISOLONE	190 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	27 / NC/3/MEET/Sep/202425/9													
Case Status	Case Approved													
Party Name	CUTCH OIL AND ALLIED INDUSTRIES 1949 PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM REVIW000000966AM24													
RA File Number	02AA04007136 AM22													
Licence No and Date	0211000893/05/07/2021													
Norms Committee Decision:														
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 border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>REFINED CLAY(SMECTONE CLAY (ODF POWDER)</td> <td>1 kg.</td> <td>1</td> <td>QUATERNARY AMMONIUM SALT</td> <td>0.447 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	REFINED CLAY(SMECTONE CLAY (ODF POWDER)	1 kg.	1	QUATERNARY AMMONIUM SALT	0.447 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
REFINED CLAY(SMECTONE CLAY (ODF POWDER)	1 kg.	1	QUATERNARY AMMONIUM SALT	0.447 kg.										

			(Activity 75+1% as per CoA)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	28 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	CUTCH OIL AND ALLIED INDUSTRIES 1949 PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00000967AM24
RA File Number	02AA04015335 AM22
Licence No and Date	0211001003/28/07/2021

Norms Committee Decision:

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.
REFINED CLAY (SMECTONE CLAY (ODF POWDER)	1 kg.	1	QUATERNARY AMMONIUM SALT (Activity 75+1% as per CoA)	0.447 kg.

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

Case No.	29 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024

and Date	
HQ File Number	HQRNORM APPLY 00192148AM22
RA File Number	03AA04091496 AM22
Licence No and Date	0311007180/23/09/2021
Norms Committee Decision: Decision: The Committee considered the request of firm for fixation of ad-hoc norms and it was observed that during the Personal Hearing held on 16/05/2024, the firm was advised to furnish the following information/documents, however, the same is still not received from the firm. Therefore, it was decided that the firm may be given last chance to furnish the following documents: i. Complete batch chemical reaction showing description of export and import item along with percentage yield on molar basis. ii. Certificate of Analysis (CoA) of import item to explain the complete description of import item No.1.	

Case No.	30 / NC/3/MEET/Sep/202425/9													
Case Status	Case Approved													
Party Name	KRITI NUTRIENTS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM REVIW00001036AM25													
RA File Number	56AA04005794 AM22													
Licence No and Date	5611000556/12/10/2021													
Norms Committee Decision:														
Decision: The Committee considered the case as per agenda and it was decided to revise 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>Soya Lecithin Liquid Food Grade (Non GMO)</td><td>1 kg.</td><td>1</td><td>Soya Lecithin Liquid</td><td>1.00 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Soya Lecithin Liquid Food Grade (Non GMO)	1 kg.	1	Soya Lecithin Liquid	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Soya Lecithin Liquid Food Grade (Non GMO)	1 kg.	1	Soya Lecithin Liquid	1.00 kg.										
RA concerned may take further necessary action as above decision of NC.														

Case No.	31 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00008200AM24
RA File Number	05AA040108247 AM22
Licence No and Date	0511006681/07/12/2021
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was observed that the firm has not furnished the proper justification for enhancement of ad-hoc norms as earlier ad-hoc norms were fixed based on the Annexure to Appendix-4E.Hence, the committee has decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents:- I. Drug Manufacturing Licence with approved composition. II. Master-Batch Formula for each export. III. Certificate of Analysis of import item.	

Case No.	32 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	SUMAR BIOTECH LLP
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00000315AM25
RA File Number	08AX04000034 AM22
Licence No and Date	0811003488/20/12/2021
Norms Committee Decision:	
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:-	

Fosfomycin Calcium EP	1 kg.	1	Fosfomycin Phenethylamine	1.635 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	33 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00008265AM24
RA File Number	05AX04000189 AM22
Licence No and Date	0511007079/21/12/2021
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was observed that the firm has not furnish the proper justification for enhancement of ad-hoc norms as earlier ad-hoc norms were fixed based on the Annexure to Appendix-4E. Hence, the committee has decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with following information / documents from the firm:- I. Drug Manufacturing Licence with approved composition. II. Master-Batch Formula for each export. III. Certificate of Analysis of import item.	

Case No.	34 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00293146AM22
RA File Number	34AX04000029 AM22
Licence No and Date	3411001569/21/12/2021
Norms Committee Decision:	

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.
SORBIC ACID 50(ENCAPSULATED SORBIC ACID 50 WITH VEGETABLE FAT)	300 MT	1	SORBIC ACID	150.0 MT
SORBIC ACID 85(ENCAPSULATED SORBIC ACID 85 WITH VEGETABLE FAT)	300 MT	2	SORBIC ACID	255.0 MT

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

Case No.	35 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	PANACEA BIOTEC PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00005946AM24
RA File Number	05AX04000321 AM22
Licence No and Date	0511007823/11/01/2022
Norms Committee Decision: Decision: The Committee considered the case as per agenda and as per the advise of Department of Bio-Technology, it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant documents from the firm.	

Case No.	36 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	GANGWAL HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024

HQ File Number	HQRNORM APPLY 00356909AM22
RA File Number	03AX04001205 AM22
Licence No and Date	0311011422/16/02/2022
Norms Committee Decision: Decision: The Committee considered the case as per agenda and it was observed that the firm has given CoA of many formulations which are not shown in Advance Authorisation. It is difficult to formulate a view on the final norms. Therefore, it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith following documents: 1. Export description is vogue and does not indicate percentage DHA in export. 2. Import item No.1 is confusing as it does not indicate percentage Assay. 3. Whether import and export are Oil Powder. If so, please get the license amended as per 1 to 3 above.	

Case No.	37 / NC/3/MEET/Sep/202425/9													
Case Status	Case Approved													
Party Name	GUPTA AROMATICS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM REVIW00009287AM24													
RA File Number	05AX04001230 AM22													
Licence No and Date	0511010862/10/03/2022													
Norms Committee Decision:														
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. 10/82-ALC4/2019 dated 29/11/2019 against advance authorization No. 0510403552 dated 01/08/2017 , 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>CARVACROL</td><td>1 kg.</td><td>1</td><td>D-LIMONENE (1 methyl-4-(1-methylenyl)-cyclobexene)</td><td>1.48 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CARVACROL	1 kg.	1	D-LIMONENE (1 methyl-4-(1-methylenyl)-cyclobexene)	1.48 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
CARVACROL	1 kg.	1	D-LIMONENE (1 methyl-4-(1-methylenyl)-cyclobexene)	1.48 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	38 / NC/3/MEET/Sep/202425/9										
Case Status	Case Approved										
Party Name	GUPTA AROMATICS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024										
HQ File Number	HQRNORM REVIW00009288AM24										
RA File Number	05AX04001267 AM22										
Licence No and Date	0511010970/14/03/2022										
Norms Committee Decision:											
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. 10/82-ALC4/2019 dated 29/11/2019 against advance authorization No. 0510403552 dated 01/08/2017 , 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>CARVACROL</td><td>1 kg.</td><td>1</td><td>D-LIMONENE (1 methyl-4-(1-methylenyl)-cyclobexene)</td><td>1.48 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CARVACROL	1 kg.	1	D-LIMONENE (1 methyl-4-(1-methylenyl)-cyclobexene)	1.48 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
CARVACROL	1 kg.	1	D-LIMONENE (1 methyl-4-(1-methylenyl)-cyclobexene)	1.48 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	39 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	PROEC ENERGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00005029AM24
RA File Number	05AX04001262 AM22
Licence No and Date	0511010975/14/03/2022
Norms Committee Decision:	

Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:-

- I. Stoichiometric balance between import and export on molar basis.
- II. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.

Case No.	40 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00001720AM23
RA File Number	33AX04000021 AM23
Licence No and Date	3311000772/28/06/2022

Norms Committee Decision:

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.
Meropenem Sodium Sterile (Meropenem for injection)	1 kg.	1	4-Nitrobenzyl (5S,6S)-3-(((3S,5S)-5-((Dimethylamino) Carbonyl)-1(((4nitrobenzyl oxy) Carbonyl)pyrrolidinyl) sulfanyl]-6-((1R)-1-hydroxyethyl)-4-methyl-7-oxo-1-azabicyclo (3.2.0) hept2-ene-2-carboxylate	0.8457 kg.

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

Case No.	41 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00002221AM23
RA File Number	07AX04000559 AM23
Licence No and Date	0711004755/23/07/2022
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- i. To give chemistry of the reaction indicating molecular weight of both reactant and product. ii. Yield of the reaction with end use of the export item.	

Case No.	42 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00006414AM24
RA File Number	09AX04000207 AM23
Licence No and Date	0911003443/05/08/2022
Norms Committee Decision: Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	43 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00002944AM23
RA File Number	07AX04000812 AM23
Licence No and	0711005159/05/09/2022

Date																																															
Norms Committee Decision:																																															
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.1/NC/3/MEET/Dec/202223/15dated 29/12/2022 against advance authorization No. 0711004348 dated 17/06/2022, 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:-																																															
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>MAGNESIUM LACTATE GLUCONATE</td> <td>1 kg.</td> <td>1</td> <td>GLUCONO DELTA LACTONE</td> <td>0.755 kg.</td> </tr> <tr> <td>ZINC GLUCONATE (Eur.Ph/USP)</td> <td>1 kg.</td> <td>2</td> <td>GLUCONO DELTA LACTONE</td> <td>0.945 kg.</td> </tr> <tr> <td>MAGNESIUM GLUCONATE (Eur.Ph/USP)</td> <td>1 kg.</td> <td>3</td> <td>GLUCONO DELTA LACTONE</td> <td>0.945 kg.</td> </tr> <tr> <td rowspan="2">POTASSIUM GLUCONATE (USP)</td> <td rowspan="2">1 kg.</td> <td>4</td> <td>GLUCONO DELTA LACTONE</td> <td>0.930 kg.</td> </tr> <tr> <td>8</td> <td>POTASSIUM CARBONATE GRANULAR</td> <td>Deleted.</td> </tr> <tr> <td>FERROUS GLUCONATE (BP/EP/USP)</td> <td>1 kg.</td> <td>5</td> <td>GLUCONO DELTA LACTONE</td> <td>0.887 kg.</td> </tr> <tr> <td>MANGANESE GLUCONATE (Eur.Ph/USP)</td> <td>1 kg.</td> <td>6</td> <td>GLUCONO DELTA LACTONE</td> <td>0.945 kg.</td> </tr> <tr> <td>CALCIUM MAGNESIUM LACTATE GLUCONATE</td> <td>1 kg.</td> <td>7</td> <td>GLUCONO DELTA LACTONE</td> <td>0.831 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	MAGNESIUM LACTATE GLUCONATE	1 kg.	1	GLUCONO DELTA LACTONE	0.755 kg.	ZINC GLUCONATE (Eur.Ph/USP)	1 kg.	2	GLUCONO DELTA LACTONE	0.945 kg.	MAGNESIUM GLUCONATE (Eur.Ph/USP)	1 kg.	3	GLUCONO DELTA LACTONE	0.945 kg.	POTASSIUM GLUCONATE (USP)	1 kg.	4	GLUCONO DELTA LACTONE	0.930 kg.	8	POTASSIUM CARBONATE GRANULAR	Deleted.	FERROUS GLUCONATE (BP/EP/USP)	1 kg.	5	GLUCONO DELTA LACTONE	0.887 kg.	MANGANESE GLUCONATE (Eur.Ph/USP)	1 kg.	6	GLUCONO DELTA LACTONE	0.945 kg.	CALCIUM MAGNESIUM LACTATE GLUCONATE	1 kg.	7	GLUCONO DELTA LACTONE	0.831 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																																											
MAGNESIUM LACTATE GLUCONATE	1 kg.	1	GLUCONO DELTA LACTONE	0.755 kg.																																											
ZINC GLUCONATE (Eur.Ph/USP)	1 kg.	2	GLUCONO DELTA LACTONE	0.945 kg.																																											
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CALCIUM MAGNESIUM LACTATE GLUCONATE	1 kg.	7	GLUCONO DELTA LACTONE	0.831 kg.																																											
RA concerned may take further necessary action as per above decision of NC.																																															

Case No.	44 / NC/3/MEET/Sep/202425/9													
Case Status	Case Approved													
Party Name	KRITI NUTRIENTS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM REVIW00001037AM25													
RA File Number	56AX04000172 AM23													
Licence No and Date	5611001168/15/09/2022													
Norms Committee Decision:														
Decision: The Committee considered the case as per agenda and it was decided to revise 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>Soya Lecithin Liquid Food Grade (Non GMO)</td><td>1 kg.</td><td>1</td><td>Soya Lecithin Liquid</td><td>1.00 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Soya Lecithin Liquid Food Grade (Non GMO)	1 kg.	1	Soya Lecithin Liquid	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Soya Lecithin Liquid Food Grade (Non GMO)	1 kg.	1	Soya Lecithin Liquid	1.00 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	45 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	KAVALIFE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00003326AM23
RA File Number	07AX04000884 AM23
Licence No and Date	0711005312/23/09/2022
Norms Committee Decision:	
Decision: The firm was called for Personal Hearing on 08.08.2024 through Video Conference but the firm could not appear before Norms Committee. It was decided to grant one more opportunity to the firm for <u>Personal Haring</u> with relevant documents.	

Case No.	46 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00003358AM23
RA File Number	03AX04002988 AM23
Licence No and Date	0311018145/25/09/2022
Norms Committee Decision: Decision:The Committee considered the request of firm for fixation of ad-hoc norms and it was observed that during the Personal Hearing held on 05/03/2024, the firm informed that they are getting many intermediates manufactured by their supporting manufacturer, details for which was not given. The firm also could not explain the confusion raised by committee in the yields claim in the process. Keeping the above issued in mind the firm stated that they would come with revised application and revised license. However, the firm still not submitted the same. Therefore, it was decided that the firm may be given last chance to furnish the revised application and license.	

Case No.	47 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	VASISTA LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004049AM23
RA File Number	09AX04000675 AM23
Licence No and Date	0911003903/03/11/2022
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Item of import is a solvent, please indicate total quantity used in the process to manufacturing 1 kg. of export and recovery of Tetra Hydro Furan duly certified byChartered Chemical Engineer.	

Case No.	48 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004071AM23
RA File Number	09AX04000645 AM23
Licence No and Date	0911003906/04/11/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	49 / NC/3/MEET/Sep/202425/9													
Case Status	Case Approved													
Party Name	AMARA LABS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM APPLY 00004072AM23													
RA File Number	09AX04000646 AM23													
Licence No and Date	0911003907/04/11/2022													
Norms Committee Decision:														
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/Dec/202324/19 dated 05/01/2024 against advance authorization No.0911001711dated 13/10/2021, 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:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr><tr><td>DEFERIPRONE</td><td>1 kg.</td><td>1</td><td>Maltol</td><td>1.26 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DEFERIPRONE	1 kg.	1	Maltol	1.26 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
DEFERIPRONE	1 kg.	1	Maltol	1.26 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	50 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004212AM23
RA File Number	05AX04002149 AM23
Licence No and Date	0511015679/09/11/2022

Norms Committee Decision:

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/Apr/202425/1 dated 10/04/2024** against advance authorization **No. 0311008816 dated 24/11/2021** , 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.
Propionic Anhydride	1 kg.	1	Propionic Acid	1.15 kg.
		2	Acetic Acid Glacial	0.543 kg.

Note: Norms Committee also decided to make Standard Input Output Norms (SION) for the above export products based on ad-hoc norms.

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

Case No.	51 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	VACHICHEM INTERNATIONAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004219AM23
RA File Number	07AX04001122 AM23
Licence No and Date	0711005637/09/11/2022
Norms Committee Decision:	

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/Apr/202324/1** dated **28/04/2023** against advance authorization **No. 0711006018** dated **26/12/2022**, 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.
6-(2-PROPENY)-ERGOLINE-8-CARBOXYLIC ACID CAS NO 81409-74-7	1 kg.	1	LYSERGOL (9,10 DIDEHYDRO 6 METHYLERGOLINE -8B-METHANOL CAS NO 602-85-7)	2.98 kg.

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

Case No.	52 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004250AM23
RA File Number	05AX04002186 AM23
Licence No and Date	0511015716/09/11/2022

Norms Committee Decision:

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.
Imipenem and Cilastatin for injection USP(Sterile Bulk)	1 kg.	1	Cilastatin Acid	0.489 kg.
		2	Imipenem Monohydrate Non Sterile	0.576 kg.

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

Case No.	53 / NC/3/MEET/Sep/202425/9													
Case Status	Case Approved													
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM REVIW00008380AM24													
RA File Number	09AX04000689 AM23													
Licence No and Date	0911003913/09/11/2022													
Norms Committee Decision:														
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="2">BENZOPHENONE-3</td><td rowspan="2">1 kg.</td><td>1</td><td>RESORCINOL</td><td>0.60 kg.</td></tr><tr><td>2</td><td>BENZOTRICHLORIDE</td><td>1.07 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	BENZOPHENONE-3	1 kg.	1	RESORCINOL	0.60 kg.	2	BENZOTRICHLORIDE	1.07 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
BENZOPHENONE-3	1 kg.	1	RESORCINOL	0.60 kg.										
		2	BENZOTRICHLORIDE	1.07 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	54 / NC/3/MEET/Sep/202425/9										
Case Status	Case Approved										
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024										
HQ File Number	HQRNORM APPLY 00004258AM23										
RA File Number	03AX04003990 AM23										
Licence No and Date	0311019120/10/11/2022										
Norms Committee Decision:											
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>PARACETAMOL COATED GRANULES (89.29%)</td><td>1 kg.</td><td>1</td><td>PARACETAMOL EP</td><td>0.9018 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PARACETAMOL COATED GRANULES (89.29%)	1 kg.	1	PARACETAMOL EP	0.9018 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
PARACETAMOL COATED GRANULES (89.29%)	1 kg.	1	PARACETAMOL EP	0.9018 kg.							

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

Case No.	55 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004409AM23
RA File Number	03AX04003954 AM23
Licence No and Date	0311019281/17/11/2022
Norms Committee Decision:	
Decision: The committee considered the request of firm for fixation of ad-hoc norms and it has been observed that composition of export item in DML is not readable. Hence, it was decided that the firm may be advised to give clear copy of DML.	

Case No.	56 / NC/3/MEET/Sep/202425/9			
Case Status	Case Approved			
Party Name	ENVEE DRUGS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024			
HQ File Number	HQRNORM APPLY 00004428AM23			
RA File Number	34AX04000741 AM23			
Licence No and Date	3411003006/17/11/2022			
Norms Committee Decision:				
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.
DEXAMETHASONE (IP/ BP/ USP)	1 kg.	1	16 ALFA METHYL EXOXIDE 8DM	0.811 kg.

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

Case No.	57 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004437AM23
RA File Number	03AX04003955 AM23
Licence No and Date	0311019320/18/11/2022
Norms Committee Decision:	
Decision: The committee considered the request of firm for fixation of ad-hoc norms and it has been observed that composition of export item in DML is not readable. Hence, it was decided that the firm may be advised to give clear copy of DML	

Case No.	58 / NC/3/MEET/Sep/202425/9			
Case Status	Case Approved			
Party Name	BIOLOGICAL E. LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024			
HQ File Number	HQRNORM APPLY 00004512AM23			
RA File Number	09AX04000684 AM23			
Licence No and Date	0911003996/21/11/2022			
Norms Committee Decision:				
Decision: The Committee considered the case as per comments of Deptt. of Bio-Technology, 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.
HEPARIN SODIUM BP/USP	100 kg.	1	HEPARIN SODIUM CRUDE (BOVINE ORIGIN)	114 kg.

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

Case No.	59 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004509AM23
RA File Number	09AX04000587 AM23
Licence No and Date	0911003994/21/11/2022

Norms Committee Decision:

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.
Clavamox Drops 62.50 mg/mL - 15 mL Bottle(Amoxicillin/ Clavulanic Acid 50/12.5 mg/mL (Each mL contains Amoxicillin Trihydrate equivalent to Amoxicillin 50 mg and Clavulanate potassium syloid Blend 1:1 equivalent to Clavulanic acid 12.5mg))	1008000 Numbers	1	Amoxicillin Trihydrate	885.00 kg.
		2	Potassium Clavulanate diluted with Silicon Dioxide (Syloid)(1:1)	459.30 kg.

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

Case No.	60 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004522AM23

RA File Number	08AX04001395 AM23			
Licence No and Date	0811006510/22/11/2022			
Norms Committee Decision:				
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.
Levoleucovorin Injection 1756900 mg/17.5 mL (10 mg/mL)	Numbers	1	CALCIUM LEVOFOLINATE CONFORMING TO EP	1.35 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	61 / NC/3/MEET/Sep/202425/9			
Case Status	Case Approved			
Party Name	AUROBINDO PHARMA LTD			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024			
HQ File Number	HQRNORM APPLY 00004555AM23			
RA File Number	09AX04000691 AM23			
Licence No and Date	0911004009/23/11/2022			
Norms Committee Decision:				
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.
Acebutolol Tablets 200 mg([Each film coated tablet contains Acebutolol Hydrochloride Ph.Eur equivalent toAcebutolol 200mg])	1 Number	1	Acebutolol Hydrochloride Ph.Eur	221.698 mg
Acebutolol Tablets 400 mg([Each film coated tablet contains Acebutolol Hydrochloride Ph.Eur equivalent	1 Number	2	Acebutolol Hydrochloride Ph.Eur	443.396 mg

toAcebutolol 400mg))

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

Case No.	62 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004575AM23
RA File Number	31AX04000236 AM23
Licence No and Date	3111001838/24/11/2022

Norms Committee Decision:

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.
METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 86.66% W/W WHITE GRANULES POWDER	1 kg.	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.484 kg.
		2	SODIUM STARCH GLYCOLATE WHITE POWDER	0.034 kg.

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

Case No.	63 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	NICHINO INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004577AM23
RA File Number	09AX04000753 AM23
Licence No and Date	0911004012/24/11/2022
Norms Committee Decision:	

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.
SOD {N-(1,1-DIMETHYL-2-METHYLSULFINYLETHY)-N-{2-METHYL-4-{1,2,2,2- TETRAFLUORO-1-{TRIFLUOROMETHYL)ETHYL]PHENYL PHTHALAMI(NA)	1 kg.	1	Phthaloyl dichloride (PDC) - 98% min.	0.469 kg.
		2	2-methyl-1-methylthio-propan-2-amine (SAA) - 95% min.	0.309 kg.
		3	2-Methyl-4-heptafluoroisopropyl aniline [RFA]-96% min.	0.5645 kg.

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

Case No.	64 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	VIRCHOW DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004590AM23
RA File Number	09AX04000666 AM23
Licence No and Date	0911004017/24/11/2022

Norms Committee Decision:

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/Apr/202324/1** dated **28/04/2023** against advance authorization **No. 0711006018** dated **26/12/2022**, 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.
TELMISARTAN	1 kg.	1	2-N-PROPYL-4-METHYL-6-(1-METHYLBENZIMIDAZOLE-2-YL) BENZIMIDAZOLE	0.621 kg

		2	2-CYANO-4-METHYLBIPHENYL(OTBN)	0.630 kg.
		3	Acetone	0.20 kg.
		4	Sodium Hydroxide Flakes	0.60 kg.
		5	n-Butanol	0.80 kg.
		6	Methanol	2.80 kg.
		7	Acetic Acid	0.89 kg.
		8	Potassium Hydroxide Flakes (KOH flakes)	0.185 kg.
		9	Methylene Chloride	0.50 kg.

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

Case No.	65 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	NICHINO INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004625AM23
RA File Number	09AX04000754 AM23
Licence No and Date	0911004025/28/11/2022

Norms Committee Decision:

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.
SOD {N-(1,1-DIMETHYL-2-METHYLSULFINYLETHY)-N?{2-	1 kg.	1	PHTHALOYI DICHLORIDE (PDC)	0.469 kg.

METHYL-4-{1,2,2,2-TETRAFLUORO-1-{TRIFLUOROMETHYL}ETHYL]PHENYL PHTHALAMID(NA)		2	2. 2-METHYL-1-METHYLTHIO-PROPAN-2-AMINE (SAA)	0.309 kg.
		3	2-METHYL-4-HEPTAFLUOROISOPROPYL ANILINE((RFA) 96% MIN	0.5645 kg.

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

Case No.	66 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004648AM23
RA File Number	09AX04000768 AM23
Licence No and Date	0911004035/28/11/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	67 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004687AM23
RA File Number	09AX04000763 AM23
Licence No and Date	0911004042/29/11/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	68 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004728AM23
RA File Number	03AX04004201 AM23
Licence No and Date	0311019658/01/12/2022

Norms Committee Decision:

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/Dec/202324/17** dated **20/12/2023** against advance authorization **No. 0311017046 dated 10/08/2022**, 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.
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.	69 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004798AM23

RA File Number	03AX04004191 AM23			
Licence No and Date	0311019737/03/12/2022			
Norms Committee Decision:				
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/Jan/202324/21 dated 24/01/2024 against advance authorization No. 0311023793 dated 23/05/2023, 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. allowed.
LIOTHRONINE SODIUM 5 MCG TABLETS	1 Number	1	Liothyronine sodium	5.10 MCG per 5 MCG Tablet
LIOETHYRONINE SODIUM 10 MCG TABLETS	1 Number	2	Liothyronine sodium	10.20 MCG per 10 MCG Tablet
LIOETHYRONINE SODIUM 20 MCG TABLETS	1 Number	3	Liothyronine sodium	20.40 MCG per 20 MCG Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	70 / NC/3/MEET/Sep/202425/9			
Case Status	Case Approved			
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024			
HQ File Number	HQRNORM APPLY 00004828AM23			
RA File Number	09AX04000798 AM23			
Licence No and Date	0911004095/06/12/2022			
Norms Committee Decision:				
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.

Pinaverium Bromide	1 kg.	1	Dihydronopol	0.60 kg.,
		2	2-bromo-4,5-dimethoxy benzyl bromide	1.00 kg.
		3	Acetone	1.00 kg.
		4	Toulene	0.90 kg.

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

Case No.	71 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00006136AM24
RA File Number	52AX04001711 AM23
Licence No and Date	5211003710/07/12/2022
Norms Committee Decision:	
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 along with relevant documents from the firm.	

Case No.	72 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00006412AM24
RA File Number	09AX04000649 AM23
Licence No and Date	0911004131/08/12/2022
Norms Committee Decision:	
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 from the firm.

Case No.	73 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00004943AM23
RA File Number	03AX04004593 AM23
Licence No and Date	0311019936/12/12/2022

Norms Committee Decision:

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/Apr/202425/2** dated **30/04/2024** against advance authorization **No. 0311024276 dated 06/06/2023**, 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. allowed.
Carbamazepine Extended-Release Tablets USP 100 mg.(Each tablet contains (i) Carbamazepine 100 mg. (ii) CelluloseAcetate (CA-320S) - Eastman 35.04 mg. (iii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 5.28 mg Net content (i) 750 Kg (ii) 262.80Kg (iii) 39.60 Kg.)	1 Number	1	Carbamazepine	102.00 mg.
		2	Cellulose Acetate (CA-320S) Eastman	29.20 mg.
		3	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.
Carbamazepine Extended-Release Tablets USP 200 mg.(Each tablet contains (i) Carbamazepine 200 mg. (ii) CelluloseAcetate(CA-320S)- Eastman35.04mg. (iii)Eastman(TMCelluloseAcetate (CA398-10NF/EP)-5.28mg Netcontent(i)530kg (ii)92.86Kg(iii) 13.99 Kg.)	1 Number	4	Carbamazepine	204.00 mg.
		5	Cellulose Acetate (CA-320S) Eastman	29.20 mg.
		6	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.
Carbamazepine Extended-Release Tablets USP 400 mg.(Each tablet contains (i) Carbamazepine 400 mg. (ii) CelluloseAcetate(CA-320S)- Eastman26.28mg.	1 Number	7	Carbamazepine	408.00 mg.
		8	Cellulose Acetate (CA-320S) Eastman	29.20 mg.

(iii)Eastman(TMCellulose Acetate(CA398-10NF/EP)-3.96mg Netcontent(i)660 Kg.(ii)43.36Kg(ii) 6.53 Kg.)		9	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	4.40 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	74 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005018AM23
RA File Number	09AX04000828 AM23
Licence No and Date	0911004164/15/12/2022

Norms Committee Decision:

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.
Pinaverium Bromide	1 kg.	1	Dihydronopol	0.60 kg.,
		2	2-bromo-4,5-dimethoxy benzyl bromide	1.00 kg.
		3	Acetone	1.00 kg.
		4	Toulene	0.90 kg.

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

Case No.	75 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved

Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024										
HQ File Number	HQRNORM APPLY 00005247AM23										
RA File Number	08AX04001457 AM23										
Licence No and Date	0811006828/23/12/2022										
Norms Committee Decision: 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 border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> <tr> <td>DEXAMETHASONE SODIUM PHOSPHATE INJECTION, USP 10 MG/ML,1 ML</td><td>1 Number</td><td>1</td><td>DEXAMETHASONE SODIUM PHOSPHATE</td><td>11.76 mg</td></tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DEXAMETHASONE SODIUM PHOSPHATE INJECTION, USP 10 MG/ML,1 ML	1 Number	1	DEXAMETHASONE SODIUM PHOSPHATE	11.76 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
DEXAMETHASONE SODIUM PHOSPHATE INJECTION, USP 10 MG/ML,1 ML	1 Number	1	DEXAMETHASONE SODIUM PHOSPHATE	11.76 mg							

Case No.	76 / NC/3/MEET/Sep/202425/9													
Case Status	Case Approved													
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM APPLY 00005300AM23													
RA File Number	09AX04000869 AM23													
Licence No and Date	0911004207/26/12/2022													
Norms Committee Decision: 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 border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> <tr> <td rowspan="2">Pinaverium Bromide</td><td rowspan="2">1 kg.</td><td>1</td><td>Dihydranopol</td><td>0.60 kg.,</td></tr> <tr> <td>2</td><td>2-bromo-4,5-dimethoxy benzyl bromide</td><td>1.00 kg.</td></tr> </tbody> </table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Pinaverium Bromide	1 kg.	1	Dihydranopol	0.60 kg.,	2	2-bromo-4,5-dimethoxy benzyl bromide	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Pinaverium Bromide	1 kg.	1	Dihydranopol	0.60 kg.,										
		2	2-bromo-4,5-dimethoxy benzyl bromide	1.00 kg.										

		3	Acetone	1.00 kg.
		4	Toulene	0.90 kg.

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

Case No.	77 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005317AM23
RA File Number	07AX04001362 AM23
Licence No and Date	0711006024/27/12/2022

Norms Committee Decision:

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/Jun/202425/6** dated **01/07/2024** against advance authorization **No. 0711008971 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. allowed.
FERROUS FORTE TABLETS (Vitamin C (as Ascorbic Acid) - 71mg (248.500 KGS) +Iron (From Ferrous Bisglycinate Chelate- 126mg (441.000 KGS) With Other Essential Vitamins & Minerals (No of Tabs-3500000))	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.	78 / NC/3/MEET/Sep/202425/9
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Case Status	Case Approved													
Party Name	CANPEX CHEMICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM APPLY 00005335AM23													
RA File Number	31AX04000284 AM23													
Licence No and Date	3111001917/27/12/2022													
Norms Committee Decision:														
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/Jun/202425/5 dated 14/06/2024 against advance authorization No. 3111001703 dated 20/09/2022 , 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>CYANAMIDE 50% SOLUTION</td><td>1 kg.</td><td>1</td><td>CALCIUM CYANAMIDE (Purity 63% as per CoA)</td><td>1.913 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	CYANAMIDE 50% SOLUTION	1 kg.	1	CALCIUM CYANAMIDE (Purity 63% as per CoA)	1.913 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
CYANAMIDE 50% SOLUTION	1 kg.	1	CALCIUM CYANAMIDE (Purity 63% as per CoA)	1.913 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	79 / NC/3/MEET/Sep/202425/9				
Case Status	Case Approved				
Party Name	SRF LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024				
HQ File Number	HQRNORM APPLY 00005387AM23				
RA File Number	05AX04002796 AM23				
Licence No and Date	0511016607/28/12/2022				
Norms Committee Decision:					
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/Jul/202425/7 dated 06/08/2024 against advance authorization No. 0511013648 dated 07/07/2022, 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:-					
Export Product		Qty.	Sl. No.	Import Items	Qty. allowed.

PBA - (4-CHLORO 2-FLUORO 3-METHOXY PHENYL) BORONIC ACID)	1 kg.	1	2-Fluorophenol	0.83 kg.
		2	Toluene (Bulk)	0.12 kg.
		3	Lithium Metal	0.100 kg.
		4	Monoglyme (1, 2 DIMETHOXYETHANE)	0.80 kg.
		5	Mixed Hexanes	0.29 kg.
		6	Trimethyl borate	0.79 kg.

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

Case No.	80 / NC/3/MEET/Sep/202425/9													
Case Status	Case Approved													
Party Name	MEDREICH LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM APPLY 00005381AM23													
RA File Number	07AX04001433 AM23													
Licence No and Date	0711006048/28/12/2022													
Norms Committee Decision:														
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="2">ATORVASTATIN 10MG TABLETS</td><td rowspan="2">1 Number</td><td>1</td><td>ATORVASTATIN CALCIUM TRIHYDRATE</td><td>11.059 mg.</td></tr><tr><td>2</td><td>D MANNITOL</td><td>40.00 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	ATORVASTATIN 10MG TABLETS	1 Number	1	ATORVASTATIN CALCIUM TRIHYDRATE	11.059 mg.	2	D MANNITOL	40.00 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
ATORVASTATIN 10MG TABLETS	1 Number	1	ATORVASTATIN CALCIUM TRIHYDRATE	11.059 mg.										
		2	D MANNITOL	40.00 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	81 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005401AM23
RA File Number	34AX04000903 AM23
Licence No and Date	3411003211/29/12/2022
Norms Committee Decision:	
Decision: The case is under consideration and TE was requested to expedite his comments.	

Case No.	82 / NC/3/MEET/Sep/202425/9																
Case Status	Case Approved																
Party Name	STERILE INDIA PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024																
HQ File Number	HQRNORM APPLY 00005442AM23																
RA File Number	05AX04002802 AM23																
Licence No and Date	0511016635/30/12/2022																
Norms Committee Decision:																	
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="2">Imipenem and Cilastatin for injection (1:1).</td><td rowspan="2">1 kg.</td><td>1</td><td>Imipenem Monohydrate (Non Sterile)</td><td>0.576 kg.</td></tr><tr><td>2</td><td>Cilastatin Acid</td><td>0.489kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Imipenem and Cilastatin for injection (1:1).	1 kg.	1	Imipenem Monohydrate (Non Sterile)	0.576 kg.	2	Cilastatin Acid	0.489kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Imipenem and Cilastatin for injection (1:1).	1 kg.	1	Imipenem Monohydrate (Non Sterile)	0.576 kg.													
		2	Cilastatin Acid	0.489kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	83 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005487AM23
RA File Number	30AX04000416 AM23
Licence No and Date	3011002973/03/01/2023

Norms Committee Decision:

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/May/2024/25/4 dated 06/06/2024** against advance authorization **No. 3011002150 dated 23/05/2022** , 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.
Injection Urokinase (Each vial contains 500000 IU of Urokinase)	1000 Vials	1	Urokinase (purified)	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.	84 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005526AM23
RA File Number	09AX04000891 AM23

Licence No and Date	0911004257/04/01/2023
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Detailed calculation showing net requirement of import item and wastage applied thereon.	

Case No.	85 / NC/3/MEET/Sep/202425/9																						
Case Status	Case Approved																						
Party Name	RAKSHIT DRUGS PRIVATE LIMITED																						
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024																						
HQ File Number	HQRNORM APPLY 00005513AM23																						
RA File Number	09AX04000866 AM23																						
Licence No and Date	0911004255/04/01/2023																						
Norms Committee Decision:																							
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="4">Diacerein(solid)</td><td rowspan="4">1 kg.</td><td>1</td><td>Aloe Emodine 95</td><td>1.05 kg.</td></tr><tr><td>2</td><td>Di Methyl Acetamide</td><td>1.23 kg.</td></tr><tr><td>3</td><td>Di Methyl Formamide</td><td>0.93 kg.</td></tr><tr><td>4</td><td>Methanol</td><td>1.70 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Diacerein(solid)	1 kg.	1	Aloe Emodine 95	1.05 kg.	2	Di Methyl Acetamide	1.23 kg.	3	Di Methyl Formamide	0.93 kg.	4	Methanol	1.70 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																			
Diacerein(solid)	1 kg.	1	Aloe Emodine 95	1.05 kg.																			
		2	Di Methyl Acetamide	1.23 kg.																			
		3	Di Methyl Formamide	0.93 kg.																			
		4	Methanol	1.70 kg.																			
RA concerned may take further necessary action as per above decision of NC.																							

Case No.	86 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved

Party Name	MICRO LABS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024				
HQ File Number	HQRNORM APPLY 00005545AM23				
RA File Number	07AX04001477 AM23				
Licence No and Date	0711006102/05/01/2023				
Norms Committee Decision:					
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.
DICLOXACILLIN CAPSULES 250MG (64.50 KG)		1 Number	1	DICLOXACILLIN SODIUM	267.5 mg/ 250 mg Capsule
DICLOXACILLIN CAPSULES 500MG (2129.990 KG)		1 Number	2	DICLOXACILLIN SODIUM	535.0 mg/ 500 mg Capsule
RA concerned may take further necessary action as per above decision of NC.					

Case No.	87 / NC/3/MEET/Sep/202425/9			
Case Status	Case Approved			
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024			
HQ File Number	HQRNORM APPLY 00005588AM23			
RA File Number	05AX04002947 AM23			
Licence No and Date	0511016763/06/01/2023			
Norms Committee Decision:				
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:-				
a. For export item No. 1				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
BuprenorphineHydrochloride	1 kg.	1	7(Alpha)-(2-Hydroxy-3,3-Dimethyl-2-Butyl)-6, 14-Endo-Ethano-6, 7, 8, 14-	1.955 kg.

			Tetrahydronorthebaine	
		2	Cyclopropyl methanol	1.60 kg.
		3	Methane 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	50. g.

b. For export item No. 2&3

i. Norms for 1 Number Tablet.

Bulk Drug	Quantity in mg.	
	Export item no.1	Export item no.2
Buprenorphine Hydrochloride	2.04 mg.	8.16 mg.
Naloxone Hydrochloride	0.51 mg.	2.04 mg.

ii. Raw Material proposed for 1 kg. Buprenorphine Hydrochloride

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

Note: RA may work out the import entitlement of all inputs as per (i) & (ii) above on pro-rata basis.

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

Case No.	88 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005679AM23
RA File Number	08AX04001685 AM23

Licence No and Date	0811006983/11/01/2023			
Norms Committee Decision:				
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.
Magnesium Sulfate In Water for Injection (0.325 mEq Mg ⁺⁺ /mL) 40 mg/mL 2g Total	1 Number	1	Magnesium sulfate heptahydrate	2.00 gm.
Magnesium Sulfate In Water for Injection (0.325 mEq Mg ⁺⁺ /mL) 40 mg/mL 4g Total	1 Number	2	Magnesium sulfate heptahydrate	2.897 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	89 / NC/3/MEET/Sep/202425/9													
Case Status	Case Approved													
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM APPLY 00005687AM23													
RA File Number	31AX04000281 AM23													
Licence No and Date	3111001952/12/01/2023													
Norms Committee Decision:														
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="2">METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 86.66% W/W WHITE GRANULES</td><td rowspan="2">1 kg.</td><td>1</td><td>DICYANDIAMIDE (DCDA) WHITE POWDER</td><td>0.484 kg.</td></tr><tr><td>2</td><td>SODIUM STARCH</td><td>0.034 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 86.66% W/W WHITE GRANULES	1 kg.	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.484 kg.	2	SODIUM STARCH	0.034 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
METFORMIN HYDROCHLORIDE DIRECT COMPRESSIBLE GRANULES 86.66% W/W WHITE GRANULES	1 kg.	1	DICYANDIAMIDE (DCDA) WHITE POWDER	0.484 kg.										
		2	SODIUM STARCH	0.034 kg.										

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

Case No.	90 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM REVIW00004701AM24
RA File Number	07AX04001546 AM23
Licence No and Date	0711006197/16/01/2023
Norms Committee Decision:	
Decision: The committee considered the request of firm for review of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. Copy of Drug Manufacturing Licence (DML). 2. Copy of Certificate of Analysis (CoA) of import item item from Foreign Supplier.	

Case No.	91 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005762AM23
RA File Number	08AX04001684 AM23
Licence No and Date	0811007029/16/01/2023
Norms Committee Decision:	
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.
Esmolol Hydrochloride in Sodium Chloride Injection 2,500 mg/250 mL (10 mg/mL)	1 Number	1	ESMOLOL	2625 mg
Esmolol Hydrochloride in Sodium Chloride Injection [DOUBLE STRENGTH] 2,000 mg/100 mL (20 mg/mL)	1 Number	2	ESMOLOL	2100 mg

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

Case No.	92 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	PRACHI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005760AM23
RA File Number	03AX04005177 AM23
Licence No and Date	0311020750/16/01/2023

Norms Committee Decision:

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.
THIAMINE HYDROCHLORIDE	1 kg.	1	THIAMINE MONONITRATE	0.922 kg.

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

Case No.	93 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005769AM23
RA File Number	08AX04001660 AM23
Licence No and Date	0811007032/17/01/2023

Norms Committee Decision:

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.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 200 mcg per 50 mL (4 mcg/mL)(ACTIVE PHARMA INGREDIENT)	1 Number	1	DEXMEDETOMIDINE	210 mcg.
Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection 400 mcg per 100 mL (4 mcg/mL)(ACTIVE PHARMA INGREDIENT)	1 Number	2	DEXMEDETOMIDINE	420 mcg.

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

Case No.	94 / NC/3/MEET/Sep/202425/9
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005768AM23
RA File Number	05AX04003041 AM23

Licence No and Date	0511016882/17/01/2023			
Norms Committee Decision:				
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.
Formoterol Fumarate Inhalation Solution 20 mcg/2 mL (0.02 mg/2 mL),	6500000 Numbers	1	FORMOTEROL FUMARATE DIHYDRATE USP	136.50 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	95 / NC/3/MEET/Sep/202425/9			
Case Status	Case Approved			
Party Name	TOJO VIKAS INTERNATIONAL PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024			
HQ File Number	HQRNORM APPLY 00005804AM23			
RA File Number	05AX04002999 AM23			
Licence No and Date	0511016918/18/01/2023			
Norms Committee Decision:				
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.
Linalyl Acetate Refined 98 +/-2%	1 kg.	1	Linalyl Acetate	9352.6 gm
RA concerned may take further necessary action as per above decision of NC.				

Case No.	96 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	MICROTROL STERILISATION SERVICES PVT.LTD.
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005834AM23
RA File Number	07AX04001525 AM23
Licence No and Date	0711006236/19/01/2023
Norms Committee Decision: 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 along with following information / documents from the firm: 1. Copy of DML for each export item. 2. CoA of import item from foreign supplier. 3. Copy of CoA of the export item.	

Case No.	97 / NC/3/MEET/Sep/202425/9
Case Status	Case Deferred
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005825AM23
RA File Number	05AX04003069 AM23
Licence No and Date	0511016941/19/01/2023
Norms Committee Decision: Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advice of the TE, it was decided to call for following information/documents from the firm:- 1. To give proper chemical reaction starting clearly from import items asked for, in the license, giving molecular weight and name of the chemicals and also yield of the reaction. 2. Function/application of each raw material asked for, in the process indicating raw materials, catalyst solvent/diluents etc., as the case may be giving Stoichiometric material balance on molar basis. 3. The value of by-product, if any and with end use of export item.	

Case No.	98 / NC/3/MEET/Sep/202425/9
Case Status	Case Rejected
Party Name	LYRUS LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00005820AM23
RA File Number	07AX04001513 AM23
Licence No and Date	0711006229/19/01/2023
Norms Committee Decision: Decision:The Committee considered the case as per agenda and it was observed that quantity of import item is disproportionately high (12 gm. per tablet) for a tablet of 400 mg. Hence, the Committee decided to reject the case.	

Case No.	99 / NC/3/MEET/Sep/202425/9													
Case Status	Case Approved													
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024													
HQ File Number	HQRNORM APPLY 00005814AM23													
RA File Number	03AX04005159 AM23													
Licence No and Date	0311020797/19/01/2023													
Norms Committee Decision:														
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="2">Fenofibrate Bulk Granulate</td><td rowspan="2">1 Kg.</td><td>1</td><td>Fenofibrate Micronized IH/Ph.Eur</td><td>0.3155 kg.</td></tr><tr><td>2</td><td>Hypromellose (2910, 3 cps) Ph. Eur</td><td>0.0625 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Fenofibrate Bulk Granulate	1 Kg.	1	Fenofibrate Micronized IH/Ph.Eur	0.3155 kg.	2	Hypromellose (2910, 3 cps) Ph. Eur	0.0625 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Fenofibrate Bulk Granulate	1 Kg.	1	Fenofibrate Micronized IH/Ph.Eur	0.3155 kg.										
		2	Hypromellose (2910, 3 cps) Ph. Eur	0.0625 kg.										

		3	Docusate Sodium Ph.Eur	0.0062 kg.
		4	Sucrose Ph.Eur	0.3124 kg.
		5	Sodium LaurilSulfatePh.Eur	0.0216 kg.
		6	Lactose Monohydrate Ph.Eur	0.2804 kg.

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

Case No.	100 / NC/3/MEET/Sep/202425/9
Case Status	Case Withdrawn
Party Name	LYRUS LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202425/ 9 and 10/10/2024
HQ File Number	HQRNORM APPLY 00000961AM24
RA File Number	NA
Licence No and Date	0711006229/19/01/2023
Norms Committee Decision:	
Decision: The committee considered the request of the firm and observed that the firm has filed dual application on same license number as mentioned at case No.98, therefore, the committee has decided to withdraw the application of the firm.	