



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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(DES - III SECTION)**MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Sep/202324/13**DATED:** 14/09/2023Please Note

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

Meeting No. NC/3/MEET/Sep/202324/13 dated 14/09/2023 of Norms Committee - III for the year 2023-24 was held on 14/09/2023 under the Chairmanship of Rajiv Soni ,Joint DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2015-20.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	T SONGZALIAN, Deputy DGFT	DGFT(HQ)
2	UTTAM SARKAR, Assistant Section Officer	DGFT(HQ)
3	NAND Lal, Technical Consultant	DPIIT
4	SHAISH KUMAR, Technical Consultant	DGFT
5	DINESHNARAIN MATHUR, Technical Consultant	DGFT
6	Nand Lal, Technical Consultant	DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Sep/202324/13																
Case Status	Case Approved																
Party Name	STERILE INDIA PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023																
HQ File Number	HQRNORM APPLY 00002528AM24																
RA File Number	NA																
Licence No and Date	NA																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. 4/82-ALC4/2018 dated 19/06/2018 against advance authorization No.0510405555 dated07/02/2018 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty.</th></tr><tr><td rowspan="2">Piperacillin and Tazobactam sodium sterile</td><td rowspan="2">1 kg.</td><td>1</td><td>Piperacillin Acid (Intermediate)</td><td>0.891 kg.</td></tr><tr><td>2</td><td>Tazobactam Acid (Intermediate)</td><td>0.109 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Piperacillin and Tazobactam sodium sterile	1 kg.	1	Piperacillin Acid (Intermediate)	0.891 kg.	2	Tazobactam Acid (Intermediate)	0.109 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.													
Piperacillin and Tazobactam sodium sterile	1 kg.	1	Piperacillin Acid (Intermediate)	0.891 kg.													
		2	Tazobactam Acid (Intermediate)	0.109 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	2 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004206AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	3 / NC/3/MEET/Sep/202324/13			
Case Status	Case Deferred			
Party Name	INNOVASSYNTH TECHNOLOGIES (INDIA) LIMITED			
Meeting Number	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			

and Date	
HQ File Number	HQRNORM APPLY 00004450AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. To indicate name of reactants and product in the chemical reaction. 2. Certificate of Analysis (COA) report of import and export of the items. 3. Complete justification for the low yield of the reaction (at each stage), indicating the impurities/isomers/precipitation formed during the reaction. 4. Production/Consumption data duly endorsed by GST.	

Case No.	4 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004480AM23
RA File Number	NA
Licence No and Date	0910067796/null
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	5 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00005130AM23
RA File Number	072404000200 AM21
Licence No and Date	NA
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	6 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004197AM24
RA File Number	092404000413 AM12
Licence No and Date	0910050238/15/12/2011
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	7 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00007337AM23
RA File Number	039504000262 AM13
Licence No and Date	0310705888/22/08/2012
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	8 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004475AM23
RA File Number	092404000017 AM14
Licence No and Date	0910055800/19/04/2013
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	9 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred

Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00003005AM24
RA File Number	092404000287 AM14
Licence No and Date	0910057785/01/10/2013
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	10 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00003009AM24
RA File Number	092404000044 AM15
Licence No and Date	0910059969/01/05/2014
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	11 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004477AM23
RA File Number	092404000139 AM15
Licence No and Date	0910060467/17/06/2014
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	12 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00003004AM24

RA File Number	092404000421 AM15
Licence No and Date	0910061287/21/11/2014
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	13 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004605AM23
RA File Number	092404000348 AM17
Licence No and Date	0910064196/28/09/2016
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	14 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000261AM24
RA File Number	039404000617 AM17
Licence No and Date	0310808312/06/10/2016
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	15 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001056AM24
RA File Number	039404000918 AM17
Licence No and Date	0310810510/13/01/2017
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Aug/202324/11 dated 22/08/2023** against advance authorization **No.0310813394 dated 18/05/2017** , 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
N-Methyl Pyrrolidone (Purity Minimum 99.8%, Moisture Less Than 1000 PPM)	1 kg.	1	N-Methyl Pyrrolidone (Purity Maximum 86.27%, Moisture 5% to 7%)	1.23 kg.

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

Case No.	16 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	INDO AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001308AM24
RA File Number	039404001096 AM17
Licence No and Date	0310811634/06/03/2017

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Aug/202324/11 dated 22/08/2023** against advance authorization **No. 0310822662 dated 27/07/2018** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
N METHYL MORPHOLINE OXIDE 50% / IAL NMMO 50%	1 kg.	1	MORPHOLINE	0.46 kg.

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

Case No.	17 / NC/3/MEET/Sep/202324/13
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Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000263AM24
RA File Number	039404001181 AM17
Licence No and Date	0310812323/03/04/2017
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	18 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000262AM24
RA File Number	039404000295 AM18
Licence No and Date	0310814908/31/07/2017
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	19 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004483AM23
RA File Number	092404000309 AM18
Licence No and Date	0910065528/29/09/2017
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	20 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004604AM23

RA File Number	092404000430 AM18
Licence No and Date	0910065723/07/12/2017
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	21 / NC/3/MEET/Sep/202324/13													
Case Status	Case Approved													
Party Name	PAYAL POLYPLAST PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023													
HQ File Number	HQRNORM REVIW00007155AM23													
RA File Number	052404000370 AM18													
Licence No and Date	0510404862/12/12/2017													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Nov/202223/14 dated 07/12/2022 against advance authorization No. 0510405089 dated 26/12/2017 , 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><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td rowspan="2">PVC PLASTICIZER (DINP)</td><td rowspan="2">1 kg.</td><td>1</td><td>PHTHALIC ANHYDRIDE</td><td>0.372 kg.</td></tr><tr><td>2</td><td>ISO NONANOL</td><td>0.726 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	PVC PLASTICIZER (DINP)	1 kg.	1	PHTHALIC ANHYDRIDE	0.372 kg.	2	ISO NONANOL	0.726 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
PVC PLASTICIZER (DINP)	1 kg.	1	PHTHALIC ANHYDRIDE	0.372 kg.										
		2	ISO NONANOL	0.726 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	22 / NC/3/MEET/Sep/202324/13			
Case Status	Case Rejected			
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM REVIW00004486AM23			
RA File Number	092404000459 AM18			
Licence No and Date	0910065758/19/12/2017			

Norms Committee Decision:

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

Case No.	23 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00007162AM23
RA File Number	052404000447 AM18
Licence No and Date	0510405090/26/12/2017

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Nov/202223/14 dated 07/12/2022** against advance authorization **No. 0510405089 dated 26/12/2017**, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
PVC PLASTICIZER (DINP)	1 kg.	1	PHTHALIC ANHYDRIDE	0.372 kg.
		2	ISO NONANOL	0.726 kg.

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

Case No.	24 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00005115AM23
RA File Number	072404000271 AM18
Licence No and Date	0710112636/04/01/2018

Norms Committee Decision:

The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not

provided any technical justification / information for enhancement. Hence, it was decided to **reject** the case maintaining the **status quo**.

Case No.	25 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000265AM24
RA File Number	039404000822 AM18
Licence No and Date	0310818765/30/01/2018
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	26 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004481AM23
RA File Number	092404000036 AM19
Licence No and Date	0910066244/18/05/2018
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	27 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00006968AM23
RA File Number	039404000258 AM19
Licence No and Date	0310821966/27/06/2018
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	28 / NC/3/MEET/Sep/202324/13
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Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000260AM24
RA File Number	039404000753 AM19
Licence No and Date	0310825758/18/12/2018
Norms Committee Decision:	
The case is under consideration for want of comments of TE	

Case No.	29 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000752AM24
RA File Number	052404000438 AM19
Licence No and Date	0510410372/25/04/2019
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	30 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000818AM24
RA File Number	082404000026 AM20
Licence No and Date	0810145127/30/04/2019
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	31 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000154AM24
RA File Number	318304000044 AM20
Licence No and	3110067449/20/06/2019

Date	
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Complete justification of increasing the quantity of hydrogen peroxide and methanol indicating yield of reaction. 2. Production/consumption data duly endorsed by GST.	

Case No.	32 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	CONCORD BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001262AM24
RA File Number	082404000101 AM20
Licence No and Date	0810145581/27/06/2019
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	33 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004484AM23
RA File Number	092404000269 AM20
Licence No and Date	0910067906/20/08/2019
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo	

Case No.	34 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004761AM23

RA File Number	039404000395 AM20
Licence No and Date	0310831546/13/09/2019
Norms Committee Decision:	
The case is under consideration for want of factory/plant visit report from TE.	

Case No.	35 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00002001AM24
RA File Number	092404000540 AM20
Licence No and Date	0910068421/28/01/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	36 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004487AM23
RA File Number	092404000593 AM20
Licence No and Date	0910068522/27/02/2020
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	37 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00007119AM23
RA File Number	052404000024 AM21
Licence No and Date	0510414104/04/05/2020
Norms Committee Decision:	

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

Case No.	38 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00005116AM23
RA File Number	072404000032 AM21
Licence No and Date	0710116423/06/05/2020
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	39 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	OLIVE HEALTH CARE
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00007206AM23
RA File Number	039504000069 AM21
Licence No and Date	0310836213/15/05/2020
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	40 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000119AM24
RA File Number	318304000008 AM21
Licence No and Date	3110067739/19/05/2020
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jun/202223/5 dated 08/07/2022 against advance authorization No. 3111000156 dated 11/02/2021 , 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.
Anisole	1 kg.	1	Phenol	0.92 kg.
		2	Methanol	0.36 kg.

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

Case No.	41 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000814AM24
RA File Number	072404000046 AM21
Licence No and Date	0710116483/22/05/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202223/22** dated **24/03/2022** against advance authorization **No. 0711005540** dated **21/10/2022** , 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.
MAGNESIUM BISGLYCINATE MAGNESIUM GLYCINE COMPLEX	/1 kg.	1	GLYCINE	0.97 kg.
		2	MAGNESIUM OXIDE	0.26 kg.

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

Case No.	42 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023

and Date				
HQ File Number	HQRNORM REVIW00001400AM24			
RA File Number	072404000054 AM21			
Licence No and Date	0710116526/29/05/2020			
Norms Committee Decision:				
The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Case No.	43 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000095AM24
RA File Number	522404000013 AM21
Licence No and Date	5210043424/08/06/2020
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	44 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00005117AM23
RA File Number	072404000092 AM21
Licence No and Date	0710116675/29/06/2020
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Sep/202324** dated **14/09/2023** against advance authorization **No. 0710116675** dated **29/06/2020** , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
ZINC GLUCONATE - POWDER	1 kg.	1	ZINC GLUCONATE GRANULAR	-1.01 kg.

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

Case No.	45 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000121AM24
RA File Number	318304000020 AM21
Licence No and Date	3110067788/08/07/2020
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	46 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00005118AM23
RA File Number	072404000105 AM21
Licence No and Date	0710116735/13/07/2020
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo	

Case No.	47 / NC/3/MEET/Sep/202324/13
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Case Status	Case Deferred
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001550AM24
RA File Number	092404000185 AM21
Licence No and Date	0910068991/22/07/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	48 / NC/3/MEET/Sep/202324/13													
Case Status	Case Approved													
Party Name	GLOBAL CALCIUM PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023													
HQ File Number	HQRNORM REVIW00005119AM23													
RA File Number	072404000118 AM21													
Licence No and Date	0710116798/27/07/2020													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Sep/202324 dated 14/09/2023 against advance authorization No. 0710116675 dated 29/06/2020 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>ZINC GLUCONATE - POWDER</td><td>1 kg.</td><td>1</td><td>ZINC GLUCONATE - GRANULAR</td><td>1.01 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	ZINC GLUCONATE - POWDER	1 kg.	1	ZINC GLUCONATE - GRANULAR	1.01 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
ZINC GLUCONATE - POWDER	1 kg.	1	ZINC GLUCONATE - GRANULAR	1.01 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	49 / NC/3/MEET/Sep/202324/13			
Case Status	Case Deferred			
Party Name	SHIVA BIO CHEM INDUSTRIES			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM REVIW00001904AM24			
RA File Number	502404000009 AM21			

Licence No and Date	5010002703/07/08/2020
Norms Committee Decision:	
The case was under consideration for want of comments of TE.	

Case No.	50 / NC/3/MEET/Sep/202324/13																
Case Status	Case Approved																
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023																
HQ File Number	HQRNORM REVIW00000135AM24																
RA File Number	318304000034 AM21																
Licence No and Date	3110067826/14/08/2020																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Aug/202324/11 dated 22/08/2023 against advance authorization No.3110067673 dated 06/02/2020 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td rowspan="3">Acetyl Anisole (4 Methoxy Acetophenone)</td><td rowspan="3">1 kg.</td><td>1</td><td>Phenol</td><td>0.74 kg.</td></tr><tr><td>2</td><td>Methanol</td><td>0.283 kg.</td></tr><tr><td>3</td><td>Acetic Anhydride PURITY 99%</td><td>0.755 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	Acetyl Anisole (4 Methoxy Acetophenone)	1 kg.	1	Phenol	0.74 kg.	2	Methanol	0.283 kg.	3	Acetic Anhydride PURITY 99%	0.755 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.													
Acetyl Anisole (4 Methoxy Acetophenone)	1 kg.	1	Phenol	0.74 kg.													
		2	Methanol	0.283 kg.													
		3	Acetic Anhydride PURITY 99%	0.755 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	51 / NC/3/MEET/Sep/202324/13			
Case Status	Case Rejected			
Party Name	GLOBAL CALCIUM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM REVIW00005121AM23			
RA File Number	072404000146 AM21			
Licence No and Date	0710116939/28/08/2020			

Norms Committee Decision:

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

Case No.	52 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00005122AM23
RA File Number	072404000145 AM21
Licence No and Date	0710116940/28/08/2020

Norms Committee Decision:

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

Case No.	53 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001413AM24
RA File Number	072404000153 AM21
Licence No and Date	0710116971/08/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Sep/202122/8 dated 24/09/2021** against advance authorization **No. 0710115523 dated 03/10/2019**, 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.
Phenoxy Ethyl Iso Butyrate	1 kg	1	PHENOXY ETHANOL	0.70 kg.

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

Case No.	54 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000137AM24
RA File Number	318304000087 AM21
Licence No and Date	3110067912/02/11/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Aug/202324/11 dated 22/08/2023** against advance authorization **No.3110067673 dated 06/02/2020**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Acetyl Anisole (4 Methoxy Acetophenone)	1 kg.	1	Phenol	0.74 kg.
		2	Methanol	0.283 kg.
		3	Acetic Anhydride PURITY 99%	0.755 kg.

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

Case No.	55 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004763AM23
RA File Number	039404000500 AM21
Licence No and Date	0310839257/02/11/2020

Norms Committee Decision:

The case is under consideration for want of factory/plant visit report from TE.

Case No.	56 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001504AM24
RA File Number	09AA04002748 AM21
Licence No and Date	0911000023/15/12/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	57 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000254AM24
RA File Number	03AA04011698 AM21
Licence No and Date	0311000235/21/12/2020
Norms Committee Decision: The case is under consideration for want of comments of TE	

Case No.	58 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001514AM24
RA File Number	09AA04003656 AM21
Licence No and Date	0911000173/11/01/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	59 / NC/3/MEET/Sep/202324/13
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023

and Date	
HQ File Number	HQRNORM REVIW00004478AM23
RA File Number	09AA04002915 AM21
Licence No and Date	0911000179/12/01/2021
Norms Committee Decision:	
The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo .	

Case No.	60 / NC/3/MEET/Sep/202324/13																
Case Status	Case Approved																
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023																
HQ File Number	HQRNORM REVIW00001610AM24																
RA File Number	31AA04006764 AM21																
Licence No and Date	3111000201/08/03/2021																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Oct/202122/9 dated 15/10/2021 against advance authorization No. 3110067767 dated 22/06/2020 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td rowspan="2">ETHYLENE DI AMINE</td><td rowspan="2">1 kg.</td><td>1</td><td>MONOETHANOLAMINE</td><td>1.06 kg.</td></tr><tr><td>2</td><td>AMMONIA ANHYDROUS</td><td>0.294 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	ETHYLENE DI AMINE	1 kg.	1	MONOETHANOLAMINE	1.06 kg.	2	AMMONIA ANHYDROUS	0.294 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.													
ETHYLENE DI AMINE	1 kg.	1	MONOETHANOLAMINE	1.06 kg.													
		2	AMMONIA ANHYDROUS	0.294 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	61 / NC/3/MEET/Sep/202324/13			
Case Status	Case Deferred			
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM REVIW00001336AM24			
RA File Number	31AA04007907 AM21			
Licence No and	3111000255/30/03/2021			

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

Case No.	62 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001461AM24
RA File Number	07AA04004515 AM22
Licence No and Date	0711001152/21/05/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Sep/202122/8 dated 24/09/2021** against advance authorization **No. 0710115523 dated 03/10/2019**, 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.
Phenoxy Ethyl Iso Butyrate	1 kg	1	PHENOXY ETHANOL	0.70 kg.

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

Case No.	63 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00006291AM23
RA File Number	52AA04003511 AM22
Licence No and Date	5211000803/01/06/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/May/202223/4 dated 17/06/2022** against advance authorization **No.5210042463 dated**

22/12/2017, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
1-(3-CHLORO PHENYL) 4-(3-CHLORO PROPYL) PIPERAZINE HCL	1 kg.	1	1,3-BROMO CHLORO PROPANE 99 PERCENTAGE MIN	1.045 kg.

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

Case No.	64 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001319AM24
RA File Number	03AA04017165 AM22
Licence No and Date	0311004253/02/06/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	65 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001333AM24
RA File Number	03AA04018281 AM22
Licence No and Date	0311004321/04/06/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	66 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred

Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001323AM24
RA File Number	03AA04015087 AM22
Licence No and Date	0311004561/12/06/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	67 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00005688AM23
RA File Number	08AA04009431 AM22
Licence No and Date	0811001850/25/06/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	68 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004361AM24
RA File Number	34AA04002140 AM22
Licence No and Date	3411000771/28/06/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	69 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001194AM24
RA File Number	03AA04024851 AM22
Licence No and Date	0311004989/29/06/2021

Norms Committee Decision:

The case is under consideration for want of report of factory/plant visit from TE.

Case No.	70 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001292AM24
RA File Number	03AA04035672 AM22
Licence No and Date	0311005214/08/07/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	71 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001310AM24
RA File Number	03AA04025361 AM22
Licence No and Date	0311005326/12/07/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	72 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	SYNTHO CHIRALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001518AM24
RA File Number	09AA04007265 AM22
Licence No and Date	0911001194/12/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	73 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred

Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001313AM24
RA File Number	03AA04027532 AM22
Licence No and Date	0311005407/15/07/2021
Norms Committee Decision:	
The case is under consideration for want of factory/plant visit from TE.	

Case No.	74 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	CUTCH OIL AND ALLIED INDUSTRIES 1949 PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000967AM24
RA File Number	02AA04015335 AM22
Licence No and Date	0211001003/28/07/2021
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:- 1. Certificate of Analysis (COA) report of both Export and Import items indicating composition and moisture content. 2. Stage wise of wastage of Raw materials with Justification.	

Case No.	75 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001604AM24
RA File Number	31AA04000987 AM22
Licence No and Date	3111000484/28/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Aug/202324/11 dated 22/08/2023 against advance authorization No.3111000548 dated 26/08/2021, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty.
DI ETHYLENE TRI AMINE	1 kg.	1	MONO ETHANOL AMINE	1.184 kg.
		2	AMMONIA ANHYDROUS	0.165 kg.

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

Case No.	76 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001316AM24
RA File Number	03AA04060052 AM22
Licence No and Date	0311006318/22/08/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE	

Case No.	77 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001363AM24
RA File Number	03AA04063825 AM22
Licence No and Date	0311006317/22/08/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	78 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001317AM24
RA File Number	03AA04060785 AM22
Licence No and	0311006386/24/08/2021

Date	
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	79 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001355AM24
RA File Number	03AA04068130 AM22
Licence No and Date	0311006626/01/09/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	80 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001356AM24
RA File Number	03AA04074695 AM22
Licence No and Date	0311006805/08/09/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	81 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001343AM24
RA File Number	03AA04010926 AM22
Licence No and Date	0311006852/10/09/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	82 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred

Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001468AM24
RA File Number	34AA04006805 AM22
Licence No and Date	3411001099/10/09/2021
Norms Committee Decision: The Committee considered the 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.	

Case No.	83 / NC/3/MEET/Sep/202324/13										
Case Status	Case Approved										
Party Name	MACLEODS PHARMACEUTICALS LTD										
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023										
HQ File Number	HQRNORM REVIW00002093AM24										
RA File Number	03AA040106210 AM22										
Licence No and Date	0311007383/30/09/2021										
Norms Committee Decision:											
The Committee considered the request of firm for review of ad-hoc norms and on the basis of information provided by the firm, it was decided to revise ad-hoc norms as under:-											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>FAMCICLOVIR 250MG TABLETS(FAMCICLOVIR 250MG TABLETS</td><td>1 Number</td><td>1</td><td>9-(4-ACETOXY-3-ACETOXYMETHYLBUT-1YL)-2-AMINO-6-CHLOROPURINE</td><td>318.747 mg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	FAMCICLOVIR 250MG TABLETS(FAMCICLOVIR 250MG TABLETS	1 Number	1	9-(4-ACETOXY-3-ACETOXYMETHYLBUT-1YL)-2-AMINO-6-CHLOROPURINE	318.747 mg
Export Product	Qty.	Sl. No.	Import Items	Qty.							
FAMCICLOVIR 250MG TABLETS(FAMCICLOVIR 250MG TABLETS	1 Number	1	9-(4-ACETOXY-3-ACETOXYMETHYLBUT-1YL)-2-AMINO-6-CHLOROPURINE	318.747 mg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	84 / NC/3/MEET/Sep/202324/13			
Case Status	Case Deferred			
Party Name	ENCUBE ETHICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM REVIW00001306AM24			
RA File Number	03AA040109530 AM22			
Licence No and Date	0311007595/08/10/2021			

Norms Committee Decision:

The case is under consideration for want of report of factory/plant visit from TE.

Case No.	85 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001328AM24
RA File Number	03AA040109754 AM22
Licence No and Date	0311007605/10/10/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	86 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001293AM24
RA File Number	03AA040110377 AM22
Licence No and Date	0311007674/13/10/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	87 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000153AM24
RA File Number	31AA04028703 AM22
Licence No and Date	3111000643/25/10/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jun/202324/8 dated 30/06/2023 against advance authorization No.3110067929 dated 20/11/2020, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty.
1,3-Dicyclo Hexyl Carbodimide (DCC)	1 kg.	1	Cyclohexylamine (CHA)	1.41 kg.
		2	Methanol	0.08 kg.
		3	Phosphorus Qxy Chloride	1.49 kg.
		4	Ammonia	0.72 kg.

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

Case No.	88 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00002990AM24
RA File Number	03AA040110548 AM22
Licence No and Date	0311007891/25/10/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case.	

Case No.	89 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001361AM24
RA File Number	03AA040115878 AM22
Licence No and Date	0311008179/02/11/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	90 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred

Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00007115AM23
RA File Number	05AA04097736 AM22
Licence No and Date	0511006029/10/11/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	91 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001304AM24
RA File Number	03AA040120589 AM22
Licence No and Date	0311008617/17/11/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	92 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001344AM24
RA File Number	03AA040124209 AM22
Licence No and Date	0311009064/01/12/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	93 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001345AM24
RA File Number	03AA040124200 AM22
Licence No and Date	0311009326/09/12/2021

Norms Committee Decision:

The case is under consideration for want of report of factory/plant visit from TE.

Case No.	94 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001321AM24
RA File Number	03AA040130524 AM22
Licence No and Date	0311009529/16/12/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	95 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001346AM24
RA File Number	03AA040123994 AM22
Licence No and Date	0311009655/21/12/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE	

Case No.	96 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001357AM24
RA File Number	03AX04000252 AM22
Licence No and Date	0311009654/21/12/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	97 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001329AM24
RA File Number	03AX04000251 AM22
Licence No and Date	0311009744/24/12/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	98 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001354AM24
RA File Number	03AX04000229 AM22
Licence No and Date	0311009746/24/12/2021
Norms Committee Decision:	
The case is under consideration for want of report of factory/plant visit from TE.	

Case No.	99 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000165AM24
RA File Number	03AX04000308 AM22
Licence No and Date	0311009920/30/12/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE	

Case No.	100 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00005602AM23
RA File Number	08AX04000177 AM22
Licence No and Date	0811003727/10/01/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Aug/202324/11 dated 22/08/2023** against advance authorization **No. 0811002528 dated 07/09/2021**, 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.
METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	1	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	61.87 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [5 ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100 MG)	1 Number Vial	2	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	618.70 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL](EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)	1 Number Vial	3	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1237.39 mg/vial
METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL](EACH ML CONTAINS: METHOTREXATE USP 25MG)	1 Number Vial	4	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	306.867 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [20ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	5	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	590.57 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	6	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1181.15 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL](EACH ML	1 Number Vial	7	METHOTREXATE	5737.00 mg/vial

CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 13.375 KGS.])			EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	101 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001606AM24
RA File Number	31AX04000040 AM22
Licence No and Date	3111000876/14/01/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	102 / NC/3/MEET/Sep/202324/13			
Case Status	Case Approved			
Party Name	INTAS PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM REVIW00005603AM23			
RA File Number	08AX04000340 AM22			
Licence No and Date	0811003916/28/01/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Aug/202324/11 dated 22/08/2023 against advance authorization No. 0811002528 dated 07/09/2021 , 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.
METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	1	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	61.87 mg/vial

METHOTREXATE INJECTION BP 100MG/ML [5 ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100 MG)	1 Number Vial	2	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	618.70 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL](EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)	1 Number Vial	3	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1237.39 mg/vial
METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL](EACH ML CONTAINS: METHOTREXATE USP 25MG)	1 Number Vial	4	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	306.867 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [20ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	5	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	590.57 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	6	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1181.15 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 41.525 KGS.])	1 Number Vial	7	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	5737.00 mg/vial
RA concerned may take further necessary action as per above decision of NC.				

Case No.	103 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00006478AM23
RA File Number	03AX04001106 AM22

Licence No and Date	0311011140/06/02/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	104 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	EMCURE PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001969AM24
RA File Number	31AX04000077 AM22
Licence No and Date	3111001114/02/03/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	105 / NC/3/MEET/Sep/202324/13																
Case Status	Case Approved																
Party Name	ALG CHEMICALS.																
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023																
HQ File Number	HQRNORM REVIW00001466AM24																
RA File Number	03AX04000006 AM23																
Licence No and Date	0311014857/19/05/2022																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty.</th></tr><tr><td rowspan="2">Cetyl Trimethyl Ammonium Chloride Solution 30%</td><td rowspan="2">1 kg.</td><td>1</td><td>Cetyl Dimethyl Amine 60</td><td>0.2519 kg.</td></tr><tr><td>2</td><td>ISOPROPYL ALCOHOL</td><td>0.1375 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Cetyl Trimethyl Ammonium Chloride Solution 30%	1 kg.	1	Cetyl Dimethyl Amine 60	0.2519 kg.	2	ISOPROPYL ALCOHOL	0.1375 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.													
Cetyl Trimethyl Ammonium Chloride Solution 30%	1 kg.	1	Cetyl Dimethyl Amine 60	0.2519 kg.													
		2	ISOPROPYL ALCOHOL	0.1375 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	106 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000608AM24
RA File Number	05AX04000553 AM23
Licence No and Date	0511012820/26/05/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	107 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00005924AM23
RA File Number	03AX04001050 AM23
Licence No and Date	0311015297/07/06/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	108 / NC/3/MEET/Sep/202324/13			
Case Status	Case Approved			
Party Name	INTAS PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM REVIW00006409AM23			
RA File Number	08AX04000368 AM23			
Licence No and Date	0811005222/15/06/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Aug/202324/11 dated 22/08/2023 against advance authorization No. 0811002528 dated 07/09/2021 , 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:-				

METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	1	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	61.87 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [5 ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100 MG)	1 Number Vial	2	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	618.70 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL](EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)	1 Number Vial	3	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1237.39 mg/vial
METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL](EACH ML CONTAINS: METHOTREXATE USP 25MG)	1 Number Vial	4	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	306.867 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [20ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	5	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	590.57 mg/vial
METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number Vial	6	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	1181.15 mg/vial
METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 100.430 KGS.])	1 Number Vial	7	METHOTREXATE EP / BP / IP / USP / PH. EUR. (Moisture and Residual Solvents content not less than 12.49% in API)	5737.00 mg/vial
RA concerned may take further necessary action as per above decision of NC.				

Case No.	109 / NC/3/MEET/Sep/202324/13
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Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000259AM24
RA File Number	03AX04001871 AM23
Licence No and Date	0311015826/24/06/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain	

Case No.	110 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00006007AM23
RA File Number	03AX04001989 AM23
Licence No and Date	0311016055/04/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	111 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	KusuMa PharMa
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00000597AM24
RA File Number	03AX04002093 AM23
Licence No and Date	0311016291/12/07/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	112 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004233AM24
RA File Number	NA

Licence No and Date	3411002528/13/07/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/May/202324/5 dated 08/06/2023 against advance authorization No.3411002528 dated 13/07/2022, 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.
ORTHO NITRO TOLUENE	1 kg.	1	NITRIC ACID 68 PERCENT	Indigenously source
		2	TOLUENE	0.661 kg.
		3	SULPHURIC ACID 98 PERCENT	Indigenously source
		4	SODA ASH	0.012 kg.
RA concerned may take further necessary action as per above decision of NC				

Case No.	113 / NC/3/MEET/Sep/202324/13			
Case Status	Case Approved			
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM REVIW00001337AM24			
RA File Number	31AX04000114 AM23			
Licence No and Date	3111001569/19/07/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Oct/202122/9 dated 15/10/2021 against advance authorization No. 3110067767 dated 22/06/2020 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty.

ETHYLENE DI AMINE	1 kg.	1	MONOETHANOLAMINE	1.06 kg.
		2	AMMONIA ANHYDROUS	0.294 kg.

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

Case No.	114 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001228AM24
RA File Number	31AX04000136 AM23
Licence No and Date	3111001598/02/08/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	115 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00004178AM24
RA File Number	52AX04001623 AM23
Licence No and Date	5211003147/01/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	116 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00001464AM24
RA File Number	05AX04002301 AM23
Licence No and Date	0511015737/10/11/2022
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
Easyfive TT Vaccine DTwP-Hep B-Hib- Pentavalent Vaccine (Each vial of 5.0ml contains 10 dose) with Vaccine Vial Monitor	1000000 Vials	1	Diphtheria Bulk	13.33 Liter
		2	Tetanus Toxoid	5.23 Liter
		3	Pertussis Bulk	86.46 Liter
		4	Aluminium Phosphate Gel	68.75 kg.
		5	Electronic Temperature Data Logger	1262.5 Numbers
		6	Rubber Stopper	1015000 Numbers
		7	VVM Dot 14	1015000 Numbers
		8	Ags Hb Purification Mabs Column	5.4 Liter
		9	Tetanus Toxoid for Conjugation	6.15 Liter

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

Case No.	117 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM REVIW00002991AM24
RA File Number	03AX04004890 AM23
Licence No and Date	0311020522/06/01/2023
Norms Committee Decision:	

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

Case No.	118 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002509AM24
RA File Number	08AX04000510 AM24
Licence No and Date	0811008516/26/06/2023

Norms Committee Decision:

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

Case No.	119 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	SRIAM LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002537AM24
RA File Number	09AX04000261 AM24
Licence No and Date	0911005263/26/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No.0911004979 dated 08/05/2023**, 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.
(1S, 4R)-Cis-4-Amino-2-cyclopentene-1-methanol tartrate (CAP-II)	1 kg.	1	2-Azabicyclo [2.2.1] hept-5-en-3-one (Vince lactam)	1.337 kg.
		2	Sodium borohydride	0.214 kg.
		3	L(+) Tartaric acid	0.900 kg.
		4	D (-) tartaric acid	0.742 kg.

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

Case No.	120 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	SRIAM LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002538AM24
RA File Number	09AX04000263 AM24
Licence No and Date	0911005264/26/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No.0911004979 dated 08/05/2023** , 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.
(1S, 4R)-Cis-4-Amino-2-cyclopentene-1-methanol tartrate (CAP-II)	1 kg.	1	2-Azabicyclo [2.2.1] hept-5-en-3-one (Vince lactam)	1.337 kg.
		2	Sodium borohydride	0.214 kg.
		3	L(+) Tartaric acid	0.900 kg.
		4	D (-) tartaric acid	0.742 kg.

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

Case No.	121 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	SRIAM LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002539AM24
RA File Number	09AX04000262 AM24
Licence No and	0911005265/26/06/2023

Date				
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jun/202324/8 dated 30/06/2023 against advance authorization No.0911004979 dated 08/05/2023, 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.
(1S, 4R)-Cis-4-Amino-2-cyclopentene-1-methanol tartrate (CAP-II)	1 kg.	1	2-Azabicyclo [2.2.1] hept-5-en-3-one (Vince lactam)	1.337 kg.
		2	Sodium borohydride	0.214 kg.
		3	L(+) Tartaric acid	0.900 kg.
		4	D (-) tartaric acid	0.742 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	122 / NC/3/MEET/Sep/202324/13			
Case Status	Case Approved			
Party Name	SRIAM LABS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM APPLY 00002540AM24			
RA File Number	09AX04000259 AM24			
Licence No and Date	0911005266/26/06/2023			
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jun/202324/8 dated 30/06/2023 against advance authorization No.0911004979 dated 08/05/2023, 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.
(1S, 4R)-Cis-4-Amino-2-cyclopentene-1-methanol tartrate (CAP-II)	1 kg.	1	2-Azabicyclo [2.2.1] hept-5-en-3-one (Vince lactam)	1.337 kg.

		2	Sodium borohydride	0.214 kg.
		3	L(+) Tartaric acid	0.900 kg.
		4	D (-) tartaric acid	0.742 kg.

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

Case No.	123 / NC/3/MEET/Sep/202324/13																
Case Status	Case Approved																
Party Name	TADIMETY AROMATICS PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023																
HQ File Number	HQRNORM APPLY 00002555AM24																
RA File Number	07AX04000358 AM24																
Licence No and Date	0711008391/26/06/2023																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meetings No. NC/3/MEET/May/202324/5 dated 08/06/2023 and No. NC/3/MEET/Sep/202122/8 dated 24/09/2021 against advance authorization s No.0711002772 dated 31/12/2021 and No. 0710115523 dated 03/10/2019 , 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.</th></tr><tr><td rowspan="2">Phenoxy Ethyl Iso Butyrate 0.83/Kg(2-(phenoxy)ethyl 2-methylpropanoate (2-Phenoxy Ethyl Iso Butyrate) CAS NO.103-60-6)</td><td rowspan="2">1 kg.</td><td>1</td><td>PHENOXY ETHANOL</td><td>0.70 kg.</td></tr><tr><td>2</td><td>Iso Butyric Acid</td><td>0.498 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Phenoxy Ethyl Iso Butyrate 0.83/Kg(2-(phenoxy)ethyl 2-methylpropanoate (2-Phenoxy Ethyl Iso Butyrate) CAS NO.103-60-6)	1 kg.	1	PHENOXY ETHANOL	0.70 kg.	2	Iso Butyric Acid	0.498 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.													
Phenoxy Ethyl Iso Butyrate 0.83/Kg(2-(phenoxy)ethyl 2-methylpropanoate (2-Phenoxy Ethyl Iso Butyrate) CAS NO.103-60-6)	1 kg.	1	PHENOXY ETHANOL	0.70 kg.													
		2	Iso Butyric Acid	0.498 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	124 / NC/3/MEET/Sep/202324/13			
Case Status	Case Deferred			
Party Name	TADIMETY AROMATICS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM APPLY 00002558AM24			
RA File Number	07AX04000359 AM24			

Licence No and Date	0711008395/26/06/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	125 / NC/3/MEET/Sep/202324/13																
Case Status	Case Approved																
Party Name	PAYAL POLYPLAST PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023																
HQ File Number	HQRNORM APPLY 00002564AM24																
RA File Number	05AX04000851 AM24																
Licence No and Date	0511019523/26/06/2023																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. 13/82-ALC4/2018 dated 14/01/2019 against advance authorization No.0510408318 dated 02/11/2018 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td rowspan="2">PLASTICIZER (DI OCTYL PHTHALATE) (DOP)</td><td rowspan="2">1 kg.</td><td>1</td><td>Phthalic Anhydride</td><td>0.3797 kg.</td></tr><tr><td>2</td><td>2 Ethyl Hexanol</td><td>0.700 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	PLASTICIZER (DI OCTYL PHTHALATE) (DOP)	1 kg.	1	Phthalic Anhydride	0.3797 kg.	2	2 Ethyl Hexanol	0.700 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.													
PLASTICIZER (DI OCTYL PHTHALATE) (DOP)	1 kg.	1	Phthalic Anhydride	0.3797 kg.													
		2	2 Ethyl Hexanol	0.700 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	126 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	BRAWN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002565AM24
RA File Number	05AX04000837 AM24
Licence No and Date	0511019527/26/06/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.6/82-ALC4/2019 dated 16/08/2019 against advance authorization No.	

0710086623 dated 28/02/2012, 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.
Amikacin Sulphate Injection 100 mg /2ML VIAL(Clear, colourless to pale yellow solution filled in clear glass sealed vials.)	1 Number	1	Amikacin Sulphate	143.16 mg. / 2 ml. Vial
Amikacin Sulphate Injection 500 mg /2ML VIAL(Clear, colourless to pale yellow solution filled in clear glass sealed vials.)	1 Number	2	Amikacin Sulphate	715.81 mg / 2 ml Vial

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

Case No.	127 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002566AM24
RA File Number	05AX04000866 AM24
Licence No and Date	0511019528/26/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Aug/202223/6** dated **09/09/2022** against advance authorization **No. 0511008298** dated **27/01/2022**, 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.
Visallergol Eye Drops 0.2 Percent 2.5ml	1 Number Vial	1	Olopatadine HCL	5.61 mg

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

Case No.	128 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002572AM24
RA File Number	08AX04000392 AM24
Licence No and Date	0811008526/26/06/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	129 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002683AM24
RA File Number	08AX04000542 AM24
Licence No and Date	0811008532/27/06/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	130 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002690AM24
RA File Number	05AX04000863 AM24
Licence No and Date	0511019538/27/06/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Apr/202324/1 dated 28/04/2023 against advance authorization No. 0511016274 dated 09/12/2022, 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.
Brimonidine Tartrate 0.1% Solution 5ml Santabrim	942359.0 Vials	1	Brimonidine Tartrate	4.80 kg.

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

Case No.	131 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002713AM24
RA File Number	09AX04000257 AM24
Licence No and Date	0911005276/27/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Apr/202223/1** dated **29/04/2022** against advance authorization **No. 0911002161** dated **27/12/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
IBREXAFUNGERP CITRATE	1 kg.	1	ENFUMAFUNGIN	4.55 kg.

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

Case No.	132 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002728AM24
RA File Number	08AX04000519 AM24
Licence No and	0811008542/27/06/2023

Date

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Apr/202324/1** dated **28/04/2023** against advance authorization **No. 0811006808** dated **21/12/2022**, 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.
ASPIRIN TABLETS 75 MG(EACH UNCOATED TABLET CONTAINS ACETYL SALICYLIC ACID EP 75 MG)	1 Number	1	ASPIRIN (ACETYL SALICYLIC ACID) EP / BP / IP / USP / PH. EUR.	76.5 mg.
ASPIRIN ENTERIC COATED TABLETS 81 MG "ECOTRIN 81"(EACH ENTERIC COATED TABLET CONTAINS ASPIRIN BP 81 MG [IN WHICH ACTIVE INGREDIENT ASPIRIN (ACETYL SALICYLIC ACID) USED IS 1668.750 KGS.])	1 Number	2	ASPIRIN (ACETYL SALICYLIC ACID) EP / BP / IP / USP / PH. EUR.	82.62 mg

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

Case No.	133 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002734AM24
RA File Number	34AX04000232 AM24
Licence No and Date	3411003838/27/06/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	134 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023

and Date																				
HQ File Number	HQRNORM APPLY 00002740AM24																			
RA File Number	03AX04001392 AM24																			
Licence No and Date	0311024943/27/06/2023																			
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Feb/202223/20 dated 24/02/2023 against advance authorization No. 0311015346 dated 08/06/2022, 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" data-bbox="197 705 1428 1079"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="3">OCTYLATED DIPHENYLAMINE (OCD FLAKES/POWDER)</td> <td rowspan="3">1 kg.</td> <td>1</td> <td>DIPHENYLAMINE</td> <td>0.50 kg.</td> </tr> <tr> <td>2</td> <td>DI ISOBUTYLENE</td> <td>0.64 kg.</td> </tr> <tr> <td>3</td> <td>ACTIVATED CLAY.</td> <td>0.10 kg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC					Export Product	Qty.	Sl. No.	Import Items	Qty.	OCTYLATED DIPHENYLAMINE (OCD FLAKES/POWDER)	1 kg.	1	DIPHENYLAMINE	0.50 kg.	2	DI ISOBUTYLENE	0.64 kg.	3	ACTIVATED CLAY.	0.10 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.																
OCTYLATED DIPHENYLAMINE (OCD FLAKES/POWDER)	1 kg.	1	DIPHENYLAMINE	0.50 kg.																
		2	DI ISOBUTYLENE	0.64 kg.																
		3	ACTIVATED CLAY.	0.10 kg.																

Case No.	135 / NC/3/MEET/Sep/202324/13								
Case Status	Case Approved								
Party Name	ALEMBIC PHARMACEUTICALS LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023								
HQ File Number	HQRNORM APPLY 00002743AM24								
RA File Number	34AX04000227 AM24								
Licence No and Date	3411003839/27/06/2023								
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jun/202324/8 dated 30/06/2023 against advance authorization No. 3411003610 dated 21/04/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="197 1900 1428 1986"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty.</th> </tr> </thead> <tbody> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty.
Export Product	Qty.	Sl. No.	Import Items	Qty.					

Amantadine Hydrochloride capsules USP 100mg (Net content of active ingredients 540.00 kgs))	1 Number Capsule	1	Amantadine Hydrochloride USP	102.00 mg
		2	Microcrystalline cellulose (Avicel PH301)	106.00 mg
		3	Hydroxypropyl Cellulose (Klucel LF)	2.00 mg
		4	Croscarmellose Sodium (Ac-Di-Sol)	10.00 mg
		5	Colloidal Silicon Dioxide (Aerosil 200 Pharma)	1.00 mg
		6	Magnesium Stearate (Vegetable Source)	1.00 mg
Amantadine Hydrochloride Tablets USP 100mg (Net content of active ingredients 960.00 kgs))	1 Number Tablet	7	Amantadine Hydrochloride USP	102.00 mg
		8	Microcrystalline Cellulose (Avicel PH 101)	33.65 mg.
		9	Povidone (Kollidon 90F)	3.00 mg
		10	Lake Pigment HT 5285 FD&C Yellow 6 Sunset Yellow FCF Aluminum Lake	0.300 mg.
		11	Sodium Starch Glycolate (Type A) (EXPLOTAB)	4.50 mg.
		12	Povidone (K-30)	3.00 mg
		13	Colloidal Silicon Dioxide (Aerosil 200 Pharma)	0.75 mg
		14	Magnesium Stearate	0.80 mg

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

Case No.	136 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023

and Date	
HQ File Number	HQRNORM APPLY 00002856AM24
RA File Number	03AX04001411 AM24
Licence No and Date	0311024954/28/06/2023
Norms Committee Decision:	
The case is under duration for want of report of factory/plant visit from TE.	

Case No.	137 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	TERBOL LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002865AM24
RA File Number	07AX04000446 AM24
Licence No and Date	0711008410/28/06/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	138 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	LINCOLN PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002874AM24
RA File Number	08AX04000490 AM24
Licence No and Date	0811008569/28/06/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	139 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002880AM24
RA File Number	03AX04001433 AM24
Licence No and Date	0311024964/28/06/2023
Norms Committee Decision:	

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

Case No.	140 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002902AM24
RA File Number	09AX04000270 AM24
Licence No and Date	0911005295/28/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202324/8** dated **30/06/2023** against advance authorization **No. 00911004910** dated **28/04/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
IBREXAFUNGERP CITRATE	1 kg.	1	ENFUMAFUNGIN	4.55 kg.

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

Case No.	141 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00002912AM24
RA File Number	03AX04001443 AM24
Licence No and Date	0311024981/28/06/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. 14/82-aLC4/2018** dated **14/02/2019** against advance authorization **No. 0310822430** dated **19/07/2018**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
DIPENTAMETHYLENE THIURAM TETRA SULPHIDE (QUREACC DPTT)	1 kg.	1	PIPERIDINE	0.447 kg.
		2	CARBON DISULPHIDE	0.399 kg.
		3	HYDROGEN PEROXIDE	0.1 kg.

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

Case No.	142 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003111AM24
RA File Number	09AX04000258 AM24
Licence No and Date	0911005298/30/06/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	143 / NC/3/MEET/Sep/202324/13			
Case Status	Case Approved			
Party Name	RECKITT BENCKISER (INDIA) PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM APPLY 00003170AM24			
RA File Number	05AX04000885 AM24			
Licence No and Date	0511019590/30/06/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No. 0511012742 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.

DISPRIN DIRECTS/MELTS (ASPIRIN PH.EUR 300MG) ACETYL SALICYLIC ACID 300 mg Tablet (ASPIRIN)	1 Number Tablet	1	SACCHARIN BASE 55Ox	1.00 mg
		2	GLYCINE EP	133.30 mg
DISPRIN CARDIOCARE (ASPIRIN BP 100MG) ACETYL SALICYLIC ACID 100 mg Tablet (ASPIRIN)	1 Number Tablet	3	SACCHARIN BASE 55Ox	0.334 mg
		4	GLYCINE EP	44.40 mg

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

Case No.	144 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	BROOKS STERISCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003176AM24
RA File Number	34AX04000101 AM24
Licence No and Date	3411003857/30/06/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	145 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003181AM24
RA File Number	08AX04000522 AM24
Licence No and Date	0811008584/30/06/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	146 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	AROHEMA INGREDIENTS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023

and Date														
HQ File Number	HQRNORM APPLY 00003182AM24													
RA File Number	26AX04000031 AM24													
Licence No and Date	2611001006/30/06/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/May/202324/4 dated 26/05/2023 against advance authorization No. 2611000839 dated 08/02/2023 , 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty.</th></tr><tr><td rowspan="2">ORCANOX</td><td rowspan="2">1 kg.</td><td>1</td><td>SCLAREOL</td><td>1.1768 kg.</td></tr><tr><td>2</td><td>TRET AMYL ALCOHOL</td><td>1.00 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty.	ORCANOX	1 kg.	1	SCLAREOL	1.1768 kg.	2	TRET AMYL ALCOHOL	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
ORCANOX	1 kg.	1	SCLAREOL	1.1768 kg.										
		2	TRET AMYL ALCOHOL	1.00 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	147 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003729AM24
RA File Number	03AX04001457 AM24
Licence No and Date	0311025050/03/07/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	148 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003730AM24
RA File Number	03AX04001458 AM24
Licence No and Date	0311025051/03/07/2023

Norms Committee Decision:

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

Case No.	149 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003736AM24
RA File Number	03AX04001505 AM24
Licence No and Date	0311025060/03/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	150 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003750AM24
RA File Number	03AX04001478 AM24
Licence No and Date	0311025074/03/07/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
Co-codamol 8/500 tablets (Codeine Phosphate Hemihydrate 8mg and Paracetamol 500mg) (Each Tablet contains Codeine Phosphate Hemihydrate 8mg and Paracetamol 500mg (Net Wt.Codeine Phosphate Hemihydrate 48.00 KGS))	1 Number	1	Codeine Phosphate Hemihydrate	8.16 mg.
Co-codamol 15/500 tablets (Codeine Phosphate Hemihydrate 15mg and Paracetamol 500mg) (Each Tablet contains	1 Number	2	Codeine Phosphate Hemihydrate	15.30 mg.

Codeine Phosphate Hemihydrate 15mg and Paracetamol 500mg (Net Wt.Codeine Phosphate Hemihydrate 90.00 KGS))				
Co-codamol 30/500 tablets (Codeine Phosphate Hemihydrate 30mg and Paracetamol 500mg)(Each Tablet contains Codeine Phosphate Hemihydrate 30mg and Paracetamol 500mg (Net Wt.Codeine Phosphate Hemihydrate 180.00 KGS))	1 Number	3	Codeine Phosphate Hemihydrate	30.60 mg.

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

Case No.	151 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003755AM24
RA File Number	03AX04001511 AM24
Licence No and Date	0311025087/03/07/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
Co-dydramol 10/500 tablets (Dihydrocodeine Tartrate 10mg and Paracetamol 500mg Tablets)(Each Tablet contains Dihydrocodeine Tartrate 10mg and Paracetamol 500mg (Net Wt. Dihydrocodeine Tartrate 80.00 KGS))	1 Number	1	Dihydrocodeine Tartrate	10.20 mg.

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

Case No.	152 / NC/3/MEET/Sep/202324/13
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Case Status	Case Deferred
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003758AM24
RA File Number	05AX04000871 AM24
Licence No and Date	0511019606/03/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	153 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003895AM24
RA File Number	03AX04001506 AM24
Licence No and Date	0311025095/04/07/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
Co-codamol 8/500 tablets (Codeine Phosphate Hemihydrate 8mg and Paracetamol 500mg) (Each Tablet contains Codeine Phosphate Hemihydrate 8mg and Paracetamol 500mg (Net Wt. Codeine Phosphate Hemihydrate 320.00 KGS))	1 Number	1	Codeine Phosphate Hemihydrate	8.16 mg.
Co-codamol 15/500 tablets (Codeine Phosphate Hemihydrate 15mg and Paracetamol 500mg)(Each Tablet contains Codeine Phosphate Hemihydrate 15mg and Paracetamol 500mg (Net Wt.Codeine Phosphate Hemihydrate 780.00 KGS))	1 Number	2	Codeine Phosphate Hemihydrate	15.30 mg.
Co-codamol 30/500 tablets (Codeine Phosphate	1 Number	3	Codeine Phosphate	30.60 mg.

Hemihydrate 30mg and Paracetamol 500mg (Each Tablet contains Codeine Phosphate Hemihydrate 30mg and Paracetamol 500mg (Net Wt.Codeine Phosphate Hemihydrate 5220.00 KGS))			Hemihydrate	
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RA concerned may take further necessary action as per above decision of NC.

Case No.	154 / NC/3/MEET/Sep/202324/13													
Case Status	Case Approved													
Party Name	KRITI NUTRIENTS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023													
HQ File Number	HQRNORM APPLY 00003912AM24													
RA File Number	56AX04000209 AM24													
Licence No and Date	5611001998/04/07/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>Soya Lecithin Liquid Food Grade (Non GMO)</td><td>1 MT</td><td>1</td><td>Soya Lecithin Liquid</td><td>1.01 MT</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Soya Lecithin Liquid Food Grade (Non GMO)	1 MT	1	Soya Lecithin Liquid	1.01 MT
Export Product	Qty.	Sl. No.	Import Items	Qty.										
Soya Lecithin Liquid Food Grade (Non GMO)	1 MT	1	Soya Lecithin Liquid	1.01 MT										
RA concerned may take further necessary action as per above decision of NC														

Case No.	155 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003914AM24
RA File Number	04AX04000303 AM24
Licence No and Date	0411005642/04/07/2023
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No.0411005642 dated 04/07/2023**, 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.
IBUPROFEN LYSINE (LYSINATE)	1 kg.	1	IBUPROFEN	0.683 kg.
		2	DL LYSINATE 50%	0.970 kg.

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

Case No.	156 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003915AM24
RA File Number	04AX04000302 AM24
Licence No and Date	0411005643/04/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No.0411005085 dated 21/03/2023** , 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.
IBUPROFEN DC (Directly Compressible) 90 grade	1 kg.	1	IBUPROFEN	0.909 kg.

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

Case No.	157 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003926AM24
RA File Number	03AX04001301 AM24
Licence No and Date	0311025115/04/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Apr/202324/1 dated 28/04/2023** against advance authorization **No. 0311019883** dated **09/12/2022**, 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.
Colesevelam HCL for oral suspension 3.75 GM (Per Pack 30 Pouchs) (Total 35000 Packs) ((Net. Content of Colesevelam Hydrochloride is 3937.500 kgs))	35000 Packs	1	Colesevelam Hydrochloride	4134.375 kg.

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

Case No.	158 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	JUBILANT GENERICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00003937AM24
RA File Number	05AX04000876 AM24
Licence No and Date	0511019620/04/07/2023

Norms Committee Decision:

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

Case No.	159 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004114AM24

RA File Number	08AX04000579 AM24													
Licence No and Date	0811008604/05/07/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jul/202324/9 dated 28/07/2023 against advance authorization No. 0811004316 dated 08/03/2022, 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.</th> </tr> </thead> <tbody> <tr> <td>DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE MONOHYDRATE USED IS 106.000 KGS.])</td> <td>1 Number</td> <td>1</td> <td>DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR.</td> <td>102.908 mg</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE MONOHYDRATE USED IS 106.000 KGS.])	1 Number	1	DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR.	102.908 mg
Export Product	Qty.	Sl. No.	Import Items	Qty.										
DOXYCYCLINE DISPERSIBLE TABLETS 100 MG(EACH UNCOATED DISPERSIBLE TABLET CONTAINS: DOXYCYCLINE MONOHYDRATE PH.EUR. EQ. TO DOXYCYCLINE 100 MG [IN WHICH ACTIVE INGREDIENT DOXYCYCLINE MONOHYDRATE USED IS 106.000 KGS.])	1 Number	1	DOXYCYCLINE MONOHYDRATE EP / BP / IP / USP / PH. EUR.	102.908 mg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	160 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004115AM24
RA File Number	52AX04000093 AM24
Licence No and Date	5211005099/05/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	161 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004117AM24
RA File Number	08AX04000578 AM24
Licence No and Date	0811008606/05/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	162 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004118AM24
RA File Number	08AX04000580 AM24
Licence No and Date	0811008607/05/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No. 0811007811 dated 06/04/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
CLOZAPINE TABLETS 25 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 25 MG)	1 Number	1	CLOZAPINE EP / BP / IP / USP / PH. EUR.	25.50 mg/tablet
CLOZAPINE TABLETS 50 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 50 MG)	1 Number	2	CLOZAPINE EP / BP / IP / USP / PH. EUR.	51.00 mg/tablet
CLOZAPINE TABLETS 100 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 100 MG)	1 Number	3	CLOZAPINE EP / BP / IP / USP / PH. EUR.	102.0 mg/tablet
CLOZAPINE TABLETS 200 MG	1 Number	4	CLOZAPINE	204.00 mg/tablet

(EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 200 MG [IN WHICH ACTIVE INGREDIENT CLOZAPINE USED IS 570.000 KGS.])			EP / BP / IP / USP / PH. EUR.	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	163 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004119AM24
RA File Number	08AX04000584 AM24
Licence No and Date	0811008608/05/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No. 0811007811 dated 06/04/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
CLOZAPINE TABLETS 25 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 25 MG)	1 Number	1	CLOZAPINE EP / BP / IP / USP / PH. EUR.	25.50 mg/tablet
CLOZAPINE TABLETS 50 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 50 MG)	1 Number	2	CLOZAPINE EP / BP / IP / USP / PH. EUR.	51.00 mg/tablet
CLOZAPINE TABLETS 100 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 100 MG)	1 Number	3	CLOZAPINE EP / BP / IP / USP / PH. EUR.	102.0 mg/tablet

CLOZAPINE TABLETS 200 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 200 MG [IN WHICH ACTIVE INGREDIENT CLOZAPINE USED IS 1045.000 KGS.]	1 Number	4	CLOZAPINE EP / BP / IP / USP / PH. EUR.	204.00 mg/tablet
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RA concerned may take further necessary action as per above decision of NC.

Case No.	164 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004120AM24
RA File Number	08AX04000523 AM24
Licence No and Date	0811008610/05/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No. 0811007811 dated 06/04/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
CLOZAPINE TABLETS 25 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 25 MG)	1 Number	1	CLOZAPINE EP / BP / IP / USP / PH. EUR.	25.50 mg/tablet
CLOZAPINE TABLETS 50 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 50 MG)	1 Number	2	CLOZAPINE EP / BP / IP / USP / PH. EUR.	51.00 mg/tablet
CLOZAPINE TABLETS 100 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR.	1 Number	3	CLOZAPINE EP / BP / IP / USP / PH. EUR.	102.0 mg/tablet

100 MG)				
CLOZAPINE TABLETS 200 MG (EACH UNCOATED TABLET CONTAINS: CLOZAPINE PH.EUR. 200 MG [IN WHICH ACTIVE INGREDIENT CLOZAPINE USED IS 96.500 KGS.]	1 Number	4	CLOZAPINE EP / BP / IP / USP / PH. EUR.	204.00 mg/tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	165 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004173AM24
RA File Number	09AX04000306 AM24
Licence No and Date	0911005317/05/07/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Case No.	166 / NC/3/MEET/Sep/202324/13			
Case Status	Case Approved			
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED			

Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM APPLY 00004176AM24			
RA File Number	09AX04000307 AM24			
Licence No and Date	0911005318/05/07/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty.
Phosfomycin Phenyl Ethyl Amine	1 kg	1	Propargyl Alcohol	0.930 kg.
		2	R Phenylethylamine	0.943 kg.
		3	Tertiary butyl alcohol	1.840 kg.
		4	Toluene	1.939 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	167 / NC/3/MEET/Sep/202324/13			
Case Status	Case Approved			
Party Name	HETERO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM APPLY 00004221AM24			
RA File Number	09AX04000286 AM24			
Licence No and Date	0911005325/06/07/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty.

6-((5-FLUORO-2-((3,4,5-TRIMETHOXYPHENYL)AMINO)PYRIMIDIN-4-YL)AMINO)-2,2-DIMETHYL-2H-PYRIDO[3,2-B][1,4]OXAZIN-3(4H)-ONE (Saturated, acyclic, hydrocarbons.)	1 kg.	1	6-Amino-2,2-Dimethyl-2H-Pyrido [3,2-B][1,4]Oxazin-3(4H)-One	0.680 kg.
		2	5-Fluoro Pyrimidine-2,4-diol (or) 5-Fluoruracil	0.613 kg.

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

Case No.	168 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004222AM24
RA File Number	09AX04000297 AM24
Licence No and Date	0911005327/06/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	169 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004223AM24
RA File Number	09AX04000300 AM24
Licence No and Date	0911005335/06/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. 8/82-ALC4/2019** dated **20/09/2019** against advance authorization **No. 0910067300 dated 19/03/2019**, 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.
Nise Gel 20g Tube	1 Number	1	CAPSAICIN	5.10 mg/ 20 gm Tube

(Each tube contains 5 mg of Capsaicin)				
Nise Gel 50g Tube (Each tube contains 12.5 mg of Capsaicin)	1 Number	2	CAPSAICIN	12.75 mg/50 gm Tube

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

Case No.	170 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	AROCHEMA INGREDIENTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004229AM24
RA File Number	26AX04000043 AM24
Licence No and Date	2611001013/06/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/May/202324/4** dated **26/05/2023** against advance authorization **No.2611000839 dated 08/02/2023**, 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.
ORCANOX	1 kg.	1	SCLAREOL	1.1768 kg.
		2	TERT - AMYL ALCOHOL	1.00 kg.

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

Case No.	171 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	BULI CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004235AM24
RA File Number	03AX04001475 AM24

Licence No and Date	0311025181/06/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	172 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	VINEET LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004244AM24
RA File Number	09AX04000203 AM24
Licence No and Date	0911005339/06/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	173 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004246AM24
RA File Number	34AX04000258 AM24
Licence No and Date	3411003871/06/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	174 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	VISWAAT CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004250AM24
RA File Number	03AX04001561 AM24
Licence No and Date	0311025198/06/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	175 / NC/3/MEET/Sep/202324/13
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Case Status	Case Approved													
Party Name	DR.REDDY'S LABORATORIES LTD													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023													
HQ File Number	HQRNORM APPLY 00004252AM24													
RA File Number	09AX04000280 AM24													
Licence No and Date	0911005341/06/07/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jan/202223/18 dated 23/01/2023 against advance authorization No. 0911003510 dated 22/08/2022 , 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty.</th></tr><tr><td>Valganciclovir Tablets USP 450 mg</td><td>1 Number</td><td>1</td><td>Valganciclovir Hcl (USP Amorphous)</td><td>506.24 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Valganciclovir Tablets USP 450 mg	1 Number	1	Valganciclovir Hcl (USP Amorphous)	506.24 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
Valganciclovir Tablets USP 450 mg	1 Number	1	Valganciclovir Hcl (USP Amorphous)	506.24 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	176 / NC/3/MEET/Sep/202324/13													
Case Status	Case Approved													
Party Name	AURORE LIFE SCIENCES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023													
HQ File Number	HQRNORM APPLY 00004254AM24													
RA File Number	09AX04000296 AM24													
Licence No and Date	0911005348/06/07/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202223/22 dated 24/03/2023 against advance authorization No. 0911004033 dated 28/11/2022 , 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.</th></tr><tr><td>ERDOSTEINE</td><td>1 kg.</td><td>1</td><td>DL-Homocysteine thiolactone HCl</td><td>0.89 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	ERDOSTEINE	1 kg.	1	DL-Homocysteine thiolactone HCl	0.89 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
ERDOSTEINE	1 kg.	1	DL-Homocysteine thiolactone HCl	0.89 kg.										

		2	Thiodi glycolic Acid	0.81 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	177 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004286AM24
RA File Number	09AX04000315 AM24
Licence No and Date	0911005356/07/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	178 / NC/3/MEET/Sep/202324/13			
Case Status	Case Approved			
Party Name	PIRAMAL PHARMA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM APPLY 00004287AM24			
RA File Number	03AX04001565 AM24			
Licence No and Date	0311025232/07/07/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Apr/202324/1 dated 28/04/2023 against advance authorization No. 0311020457 dated 04/01/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty.
Bempedoic Acid and Ezetimibe Fixed Dose Combination Tablets((Each Tablet content Bempedoic Acid 180mg and Ezetimibe 10mg) (Net content of Bempedoic Acid 5400.000 kgs and Ezetimibe 300.000 kgs in total Export Qty) (AA for Free of cost material as per Para 4.11 of HBP &	1 Number	1	Bempedoic Acid	189.90 mg.
		2	Ezetimibe	10.55 mg.

Para 4.19 of FTP))				
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Note: The above norms are valid only for subject to fulfillment of following conditions:

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

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

Case No.	179 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004291AM24
RA File Number	03AX04001312 AM24
Licence No and Date	0311025237/07/07/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	180 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004296AM24
RA File Number	03AX04001358 AM24
Licence No and Date	0311025245/10/07/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	181 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004297AM24
RA File Number	03AX04001495 AM24
Licence No and Date	0311025247/10/07/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
FAROPENEM SODIUM	1 kg.	1	3R,4R)-4-ACETOXY-3-[(R)-1-(T-BUTYLDIMETHYLSILYLOXY)ETHYL]-2-AZITIDINONE;4-AA(AOSA)	1.20 kg.
		2	ALLYL OXALYL CHLORIDE	1.14 kg.

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

Case No.	182 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004299AM24
RA File Number	03AX04001599 AM24
Licence No and Date	0311025255/10/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	183 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	UNIMAX LABORATORIES
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004362AM24
RA File Number	05AX04000958 AM24
Licence No and Date	0511019654/11/07/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Jun/202324/8 dated 30/06/2023 against advance authorization No. 0511018168 dated 18/04/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details	

given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty.
Amoxicillin Capsules BP, 500 mg. (Each Capsules contains Amoxicillin BP (As Trihydrate)	1 Number	1	Amoxicillin Trihydrate BP	585.282 mg
Ampicillin Capsules BP, 500 mg. (Each Capsules contains Ampicillin BP (As Trihydrate)	1 Number	2	Ampicillin Trihydrate BP	585.282 mg

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

Case No.	184 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004365AM24
RA File Number	09AX04000225 AM24
Licence No and Date	0911005377/11/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Jan/202324/6** dated **14/06/2023** against advance authorization **No. 0911004452 dated 13/02/2023**, 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.
(R)-9-[2-phosphonomethoxy) propyl] Adenine (Compounds containing a pyrimidine ring	1 kg.	1	ADENINE	0.85 kg.
		2	N,N-DIMETHYLFORMAMIDE	2.00 kg.

(whether or not hydrogenated) or piperazine ring in the structure)		3	(R)-1,2-PROPYLENE CARBONATE	0.79 kg.
		4	N-METHYL-2-PYRROLIDONE	0.21 kg.
		5	Diethyl Para Toluene Sulfonyl Oxy Methyl Phosphonate	1.00 kg.
		6	Magnesium Tert. Butoxide	1.00 kg.

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

Case No.	185 / NC/3/MEET/Sep/202324/13			
Case Status	Case Approved			
Party Name	HETERO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM APPLY 00004384AM24			
RA File Number	09AX04000287 AM24			
Licence No and Date	0911005380/12/07/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

Case No.	186 / NC/3/MEET/Sep/202324/13			
Case Status	Case Approved			
Party Name	MANKIND PHARMA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023			
HQ File Number	HQRNORM APPLY 00004391AM24			

RA File Number	05AX04001023 AM24			
Licence No and Date	0511019756/12/07/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Oct/202122/10 dated 12/11/2021 against advance authorization No. 0911000085 dated 23/12/2020, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty.
Timolol Maleate Ophthalmic Solution, USP 0.5% (5 mL)	339623 Numbers	1	TIMOLOL MALEATE USP	11778.14 gm
Timolol Maleate Ophthalmic Solution, USP 0.5% (10 mL)	169811 Numbers	2	TIMOLOL MALEATE USP	11778.10 gm
RA concerned may take further necessary action as per above decision of NC.				

Case No.	187 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004401AM24
RA File Number	34AX04000275 AM24
Licence No and Date	3411003884/13/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	188 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004404AM24
RA File Number	31AX04000095 AM24
Licence No and Date	3111002460/13/07/2023

Norms Committee Decision:

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

Case No.	189 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004405AM24
RA File Number	03AX04001674 AM24
Licence No and Date	0311025364/13/07/2023

Norms Committee Decision:

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

Case No.	190 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	UNIMAX CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004414AM24
RA File Number	03AX04001595 AM24
Licence No and Date	0311025375/13/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No.0311022366 dated 23/03/2023**, 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:-

Sl. No.	Export Product	SION No.
1	Erythromycin Base/Erythromycin	A-215
2	Erythromycin Oxime Base (Erythromycin A-9 Oxime)	A-2244

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

Case No.	191 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004431AM24
RA File Number	07AX04000565 AM24
Licence No and Date	0711008561/14/07/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
LISINOPRIL 5MG+AMLODIPINE 5MG TABLETS(LISINOPRIL 5MG+AMLODIPINE 5MG TABLETS (35.00KG))	1 Number	1	LISINOPRIL DIHYDRATE Ph.Eur	5.10 mg
		2	AMLODIPINE BESILATE BP	5.10 mg
LISINOPRIL 10MG+AMLODIPINE 5MG TABLETS(LISINOPRIL 10MG+AMLODIPINE 5MG TABLETS (37.35 KG))	1 Number	3	LISINOPRIL DIHYDRATE Ph.Eur	10.20 mg
		4	AMLODIPINE BESILATE BP	5.10 mg

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

Case No.	192 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004433AM24
RA File Number	03AX04001604 AM24
Licence No and Date	0311025397/14/07/2023
Norms Committee Decision:	

The case is under consideration for want of report of factory/plant visit from TE.

Case No.	193 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004440AM24
RA File Number	03AX04001669 AM24
Licence No and Date	0311025403/14/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	194 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004443AM24
RA File Number	03AX04001084 AM24
Licence No and Date	0311025417/14/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	195 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	BROOKS STERISCIENCE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004445AM24
RA File Number	34AX04000271 AM24
Licence No and Date	3411003892/14/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	196 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	WEXFORD LABORATORIES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004448AM24
RA File Number	07AX04000507 AM24
Licence No and Date	0711008721/14/07/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	197 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004467AM24
RA File Number	34AX04000290 AM24
Licence No and Date	3411003905/17/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Aug/202223/6** dated **09/09/2022** against advance authorization **No. 3411001739** dated **28/01/2022** , 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.
Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 5 gm Tube(Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 5 gm Tube (Net content of active ingredients 10.00 kgs and 10.00 kgs))	3000 Numbers	1	Lidocaine USP	0.382 kg.
		2	Prilocaine Base USP	0.382 kg.
Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 30 gm tube(Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 30 gm tube (Net content of active ingredients 52.500 kgs and 52.500 kgs))	261000 Numbers	3	Lidocaine USP	199.6585 kg.
		4	Prilocaine Base USP	199.6585 kg.
Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 30 gm tube(Lidocaine and Prilocaine Cream USP 2.5% and 2.5% 30 gm tube (Net content of active ingredients 52.500 kgs	1000 Numbers	5	Lidocaine USP	1.5295 kg.

and 52.500 kgs))				
Lidocaine Ointment USP 5% 35.44 gm tube(Lidocaine Ointment USP 5% 35.44 gm tube (Net content of active ingredients 70.88 kgs))	1000 Numbers	6	Lidocaine USP	1.807 kg.
Lidocaine Ointment USP 5% 50 gm jar(Lidocaine Ointment USP 5% 50 gm jar (Net content of active ingredients 75.00 kgs))	1000 Numbers	7	Lidocaine USP	2.55 kg.

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

Case No.	198 / NC/3/MEET/Sep/202324/13													
Case Status	Case Approved													
Party Name	PIRAMAL PHARMA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023													
HQ File Number	HQRNORM APPLY 00004472AM24													
RA File Number	03AX04001698 AM24													
Licence No and Date	0311025490/17/07/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>HEXAFLUOROISOPROPYL METHYL ETHER(HFMOP)</td><td>1 kg.</td><td>1</td><td>HEXA FLUORO ISO PROPANOL</td><td>0.970 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	HEXAFLUOROISOPROPYL METHYL ETHER(HFMOP)	1 kg.	1	HEXA FLUORO ISO PROPANOL	0.970 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty.										
HEXAFLUOROISOPROPYL METHYL ETHER(HFMOP)	1 kg.	1	HEXA FLUORO ISO PROPANOL	0.970 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	199 / NC/3/MEET/Sep/202324/13			
Case Status	Case Approved			
Party Name	ETERNIS FINE CHEMICALS LIMITED			

Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023																									
HQ File Number	HQRNORM APPLY 00004474AM24																									
RA File Number	03AX04001700 AM24																									
Licence No and Date	0311025497/17/07/2023																									
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202223/20 dated 24/02/2023 against advance authorization No. 0311014744 dated 17/05/2022 , 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:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl.No.</th> <th>Import items.</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td rowspan="5">COUMARIN</td> <td rowspan="5">1 kg.</td> <td>1</td> <td>PHENOL</td> <td>1.15 kg.</td> </tr> <tr> <td>2</td> <td>XYLENE</td> <td>0.50 kg.</td> </tr> <tr> <td>3</td> <td>MAGNESIUM TURNING</td> <td>0.148 kg.</td> </tr> <tr> <td>4</td> <td>PARAFORMALDEHYDE</td> <td>0.9177 kg.</td> </tr> <tr> <td>5</td> <td>ACETIC ANHYDRIDE</td> <td>0.7356 kg.</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl.No.	Import items.	Qty.	COUMARIN	1 kg.	1	PHENOL	1.15 kg.	2	XYLENE	0.50 kg.	3	MAGNESIUM TURNING	0.148 kg.	4	PARAFORMALDEHYDE	0.9177 kg.	5	ACETIC ANHYDRIDE	0.7356 kg.
Export Product	Qty.	Sl.No.	Import items.	Qty.																						
COUMARIN	1 kg.	1	PHENOL	1.15 kg.																						
		2	XYLENE	0.50 kg.																						
		3	MAGNESIUM TURNING	0.148 kg.																						
		4	PARAFORMALDEHYDE	0.9177 kg.																						
		5	ACETIC ANHYDRIDE	0.7356 kg.																						

Case No.	200 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004476AM24
RA File Number	09AX04000351 AM24
Licence No and Date	0911005426/17/07/2023
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Aug/202324/11 dated 22/08/2023 against advance authorization No.0911003827 dated 18/10/2022, 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.
HOMOSALATE	1 kg.	1	METHYL SALICYLATE	0.649 kg.

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

Case No.	201 / NC/3/MEET/Sep/202324/13
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004481AM24
RA File Number	05AX04001076 AM24
Licence No and Date	0511019795/18/07/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Apr/202324/1 dated 28/04/2023** against advance authorization **No.0511016292 dated 12/12/2022**, 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.
Mydrimax Eye Drops 5 ml Vials (Tropicamide 0.8%)	1 Number	1	Tropicamide	40.8 mg / 5 ml Vial

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

Case No.	202 / NC/3/MEET/Sep/202324/13
Case Status	Case Deferred
Party Name	AMI LIFESCIENCES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Sep/ 202324/ 13 and 14/09/2023
HQ File Number	HQRNORM APPLY 00004482AM24

RA File Number	34AX04000293 AM24
Licence No and Date	3411003888/18/07/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	