



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/Feb/202324/23

DATED: 19/02/2024

Please Note

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

Meeting No. NC/3/MEET/Feb/202324/23 dated 19/02/2024 of Norms Committee - III for the year 2023-24 was held on 19/02/2024 under the Chairmanship of Rajiv Soni ,Joint DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2015-20.

The following members were present in the meeting:-

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

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	INNOVASSYNTH TECHNOLOGIES (INDIA) LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00004450AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee to explain its case along with relevant documents from the firm.	

Case No.	2 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	GREEN PINE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006239AM24
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:- Reason for applying the export of item Beta Pinene under para 4.06 of HBP Vol.1. Chemistry of the reaction, giving molecular weight of each of reactant and product in reaction with yield. The value of By-product, if any and to give indigenous item to use in the process and accordingly to fill Annexure to Appendix-4E.	

Case No.	3 / NC/3/MEET/Feb/202324/23
Case Status	Case Rejected
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006413AM24
RA File Number	NA
Licence No and Date	NA
Norms Committee Decision:	

The committee considered the request of firm and it was observed that the firm neither submitted their application in the Head of (Review of norms) nor paid composition fees of Rs.5000/-. Therefore, the committee decided to **withdraw** the application of the firm and advised to submit their application in the Head of review of Norms on DGFT Back Office Portal.

Case No.	4 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007797AM24
RA File Number	NA
Licence No and Date	0910067796/null

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
VALACYCLOVIR HYDROCHLORIDE MONOHYDRATE(SOLID)	1 kg.	1	CARBOBENZYLOXY L VALINE CBZ L VALINE	1.1824 kg.
		2	N DICYCLOHEXYL CARBODIIMIDE DCC	1.061 kg.
		3	4 DIMETHYLAMINO PYRIDINE DMAP	0.028 kg.
		4	ACYCLOVIR	0.758 kg.

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

Case No.	5 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006953AM24
RA File Number	092404000017 AM14
Licence No and Date	0910055800/19/04/2013
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRAZODONE HYDROCHLORIDE	1 kg.	1	CRUDE TRAZODONE HYDROCHLORIDE (TRN-3)(Purity 99.89%)	1.01 kg.

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

Case No.	6 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008424AM24
RA File Number	092404000287 AM14
Licence No and Date	0910057785/01/10/2013

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. allowed.
DIVALPROEX SODIUM	1 kg.	1	N-PROPYL BROMIDE	2.19 kg.
		2	DIETHYL MALONATE.	1.42 kg.

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

Case No.	7 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024

and Date											
HQ File Number	HQRNORM REVIW00006955AM24										
RA File Number	092404000139 AM15										
Licence No and Date	0910060467/17/06/2014										
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 border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>TRAZODONE HYDROCHLORIDE</td> <td>1 kg.</td> <td>1</td> <td>CRUDE TRAZODONE HYDROCHLORIDE (TRN-3)(Purity 99.89%)</td> <td>1.01 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. allowed.	TRAZODONE HYDROCHLORIDE	1 kg.	1	CRUDE TRAZODONE HYDROCHLORIDE (TRN-3)(Purity 99.89%)	1.01 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
TRAZODONE HYDROCHLORIDE	1 kg.	1	CRUDE TRAZODONE HYDROCHLORIDE (TRN-3)(Purity 99.89%)	1.01 kg.							

Case No.	8 / NC/3/MEET/Feb/202324/23																
Case Status	Case Approved																
Party Name	OPTIMUS DRUGS PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024																
HQ File Number	HQRNORM REVIW00008333AM24																
RA File Number	092404000060 AM16																
Licence No and Date	0910061998/08/05/2015																
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.0910061955 dated 01/05/2015; it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">SOFOSBUVIR</td> <td rowspan="2">1 kg.</td> <td>1</td> <td>Cytidine,N-benzoyl-2-deoxy-2-fluoro-2-methyl-3,5-dibenzoate,(2r)</td> <td>Not required.</td> </tr> <tr> <td>2</td> <td>(2-deoxy-2-fluoro-2-C-methyluridine)</td> <td>0.87 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	SOFOSBUVIR	1 kg.	1	Cytidine,N-benzoyl-2-deoxy-2-fluoro-2-methyl-3,5-dibenzoate,(2r)	Not required.	2	(2-deoxy-2-fluoro-2-C-methyluridine)	0.87 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
SOFOSBUVIR	1 kg.	1	Cytidine,N-benzoyl-2-deoxy-2-fluoro-2-methyl-3,5-dibenzoate,(2r)	Not required.													
		2	(2-deoxy-2-fluoro-2-C-methyluridine)	0.87 kg.													

		3	N-[(S)-(2,3,4,5,6-Pentafluorophenoxy)phenoxyphosphinyl]-L-alanine 1-methylethyl ester	Not required.
		4	L-Alanine isopropyl ester hydrochloride	1.80 kg.
		5	Phenyl dichlorophosphate	1.58 kg.
		6	Pentafluorophenol	1.16 kg.

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

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

Case No.	9 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	HERBOCHEM
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008147AM24
RA File Number	092404000148 AM16
Licence No and Date	0910062238/23/06/2015

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Extract Ipecacuanha (Ipecac Conc.8% alkaloid)	1 kg.	1	Ipecacuanha (Ipecac) Roots (Dry Roots) containing minimum 2 % Alkaloids	3.636 kg.

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

Case No.	10 / NC/3/MEET/Feb/202324/23
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Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008351AM24
RA File Number	092404000328 AM16
Licence No and Date	0910062593/11/09/2015

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.0910061955 dated 01/05/2015**; it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SOFOSBUVIR	1 kg.	1	Cytidine,N-benzoyl-2-deoxy-2-fluoro-2-methyl-3,5-dibenzoate,(2r)	Not required.
		2	(2-deoxy-2-fluoro-2-C-methyluridine)	0.87 kg.
		3	N-[(S)-(2,3,4,5,6-Pentafluorophenoxy)phenoxyphosphinyl]-L-alanine 1-methylethyl ester	Not required.
		4	L-Alanine isopropyl ester hydrochloride	1.80 kg.
		5	Phenyl dichlorophosphate	1.58 kg.
		6	Pentafluorophenol	1.16 kg.

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

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

Case No.	11 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024

HQ File Number	HQRNORM REVIW00007759AM24
RA File Number	039404000497 AM16
Licence No and Date	0310799433/14/10/2015
Norms Committee Decision:	
This case was earlier approved in NC-3 meeting No. NC/3/MEET/Dec/202324/18 held on 29/12/2023 and minutes of meeting has been uploaded on the Portal of DGFT.	

Case No.	12 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007896AM24
RA File Number	072404000347 AM16
Licence No and Date	0710109255/12/01/2016
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	13 / NC/3/MEET/Feb/202324/23													
Case Status	Case Approved													
Party Name	OPTIMUS DRUGS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024													
HQ File Number	HQRNORM REVIW00008070AM24													
RA File Number	092404000143 AM17													
Licence No and Date	0910063875/30/06/2016													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the written comments of Department of Pharmaceuticals vide their O.M. No.35011/138/2016-PI (Norms) dated August, 2016 and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">SOFOSBUVIR IH</td><td rowspan="2">1 kg.</td><td>1</td><td>2-deoxy-2-fluoro-2-C-methyluridine</td><td>0.87 kg.</td></tr><tr><td>2</td><td>N-[(S)-(2,3,4,5,6-Pentafluorophenoxy)phenoxyphosphinyl]-L-alanine 1-methylethyl ester</td><td>1.92 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	SOFOSBUVIR IH	1 kg.	1	2-deoxy-2-fluoro-2-C-methyluridine	0.87 kg.	2	N-[(S)-(2,3,4,5,6-Pentafluorophenoxy)phenoxyphosphinyl]-L-alanine 1-methylethyl ester	1.92 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
SOFOSBUVIR IH	1 kg.	1	2-deoxy-2-fluoro-2-C-methyluridine	0.87 kg.										
		2	N-[(S)-(2,3,4,5,6-Pentafluorophenoxy)phenoxyphosphinyl]-L-alanine 1-methylethyl ester	1.92 kg.										

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

Case No.	14 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007908AM24
RA File Number	072404000160 AM17
Licence No and Date	0710110226/08/08/2016
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	15 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007894AM24
RA File Number	072404000182 AM17
Licence No and Date	0710110335/30/08/2016
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	16 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007903AM24
RA File Number	072404000273 AM17
Licence No and Date	0710110770/09/12/2016
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	17 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred

Party Name	BELOORBAYIR BIOTECH LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007898AM24
RA File Number	072404000374 AM17
Licence No and Date	0710111126/14/02/2017
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	18 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005925AM24
RA File Number	NA
Licence No and Date	0910065335/08/08/2017
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 along with relevant documents from the firm.	

Case No.	19 / NC/3/MEET/Feb/202324/23
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007802AM24
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/Feb/202324/23
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007800AM24

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.	21 / NC/3/MEET/Feb/202324/23
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007799AM24
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.	22 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007594AM24
RA File Number	039404001019 AM19
Licence No and Date	0310827414/01/03/2019
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and it was observed that there are four export items after amendment. However, imports are shown only for export item No.1. Therefore, it was decided to call for following information/documents from the firm:- 1. Copy of Amended Advance Authorisation. 2. Imports applied for each export item separately. 3. Drug Manufacturing License (DML) for each export item. 4. Master Batch Formula for each export items.	

Case No.	23 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	SRF LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024																						
HQ File Number	HQRNORM REVIW00000752AM24																						
RA File Number	052404000438 AM19																						
Licence No and Date	0510410372/25/04/2019																						
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:-																							
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="4">1,1,1,2-TETRAFLUOROETHANE-R-134a (340 gram can)</td><td rowspan="4">1kg</td><td>1</td><td>ETHYLENE DI CHLORIDE</td><td>1.105kg.</td></tr><tr><td>2</td><td>ACID GRADE FLUORSPAR</td><td>2.121 kg.</td></tr><tr><td>3</td><td>EMPTY CANS (340 GRAM)</td><td>Relevant as per packing policy</td></tr><tr><td>4</td><td>CAPS FOR EMPTY CANS/ TINPLATE VALVE 1/2"</td><td>Relevant as per packing policy</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	1,1,1,2-TETRAFLUOROETHANE-R-134a (340 gram can)	1kg	1	ETHYLENE DI CHLORIDE	1.105kg.	2	ACID GRADE FLUORSPAR	2.121 kg.	3	EMPTY CANS (340 GRAM)	Relevant as per packing policy	4	CAPS FOR EMPTY CANS/ TINPLATE VALVE 1/2"	Relevant as per packing policy
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																			
1,1,1,2-TETRAFLUOROETHANE-R-134a (340 gram can)	1kg	1	ETHYLENE DI CHLORIDE	1.105kg.																			
		2	ACID GRADE FLUORSPAR	2.121 kg.																			
		3	EMPTY CANS (340 GRAM)	Relevant as per packing policy																			
		4	CAPS FOR EMPTY CANS/ TINPLATE VALVE 1/2"	Relevant as per packing policy																			
RA concerned may take further necessary action as per above decision of NC.																							

Case No.	24 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006818AM24
RA File Number	082404000005 AM20
Licence No and Date	0810145144/01/05/2019
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Dec/202324/17 dated 20/12/2023 against advance authorization No.0811001850 dated 25/06/2021; it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

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

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

Case No.	25 / NC/3/MEET/Feb/202324/23
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007801AM24
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.	26 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007586AM24
RA File Number	039404000509 AM20
Licence No and Date	0310831946/01/10/2019
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	27 / NC/3/MEET/Feb/202324/23
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024

and Date	
HQ File Number	HQRNORM REVIW00007803AM24
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.	28 / NC/3/MEET/Feb/202324/23																				
Case Status	Case Approved																				
Party Name	SHREE BANKEY BEHARI LAL FLAVORS																				
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024																				
HQ File Number	HQRNORM REVIW00006894AM24																				
RA File Number	052404000005 AM21																				
Licence No and Date	0510414033/20/04/2020																				
Norms Committee Decision:																					
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																					
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed</th></tr><tr><td rowspan="3">L-MENTHOL /MENTHOL(LAVEO)/ MENTHOL(L)/LIQUID MENTHOL</td><td rowspan="3">1 kg.</td><td>1</td><td>META - CRESOL ABOVE 98.5% PURE</td><td>1.20 kg.</td></tr><tr><td>2</td><td>ISO PROPYL ALCOHOL</td><td>0.89 kg.</td></tr><tr><td>3</td><td>ARROWZYME/LIPASE AMANO IME</td><td>0.010 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed	L-MENTHOL /MENTHOL(LAVEO)/ MENTHOL(L)/LIQUID MENTHOL	1 kg.	1	META - CRESOL ABOVE 98.5% PURE	1.20 kg.	2	ISO PROPYL ALCOHOL	0.89 kg.	3	ARROWZYME/LIPASE AMANO IME	0.010 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed																	
L-MENTHOL /MENTHOL(LAVEO)/ MENTHOL(L)/LIQUID MENTHOL	1 kg.	1	META - CRESOL ABOVE 98.5% PURE	1.20 kg.																	
		2	ISO PROPYL ALCOHOL	0.89 kg.																	
		3	ARROWZYME/LIPASE AMANO IME	0.010 kg.																	
RA concerned may take further necessary action as per above decision of NC.																					

Case No.	29 / NC/3/MEET/Feb/202324/23			
Case Status	Case Deferred			
Party Name	ARENE LIFE SCIENCES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024			
HQ File Number	HQRNORM REVIW00006628AM24			

RA File Number	092404000024 AM21
Licence No and Date	0910068681/28/04/2020
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 alongwith relevant documents from the firm:	

Case No.	30 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	SHREE BANKEY BEHARI LAL FLAVORS
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006895AM24
RA File Number	052404000039 AM21
Licence No and Date	0510414144/11/05/2020

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
L-MENTHOL /MENTHOL(LAVEO)/ MENTHOL(L)/LIQUID MENTHOL	1 kg.	1	META - CRESOL ABOVE 98.5% PURE	1.20 kg.
		2	ISO PROPYL ALCOHOL	0.89 kg.
		3	ARROWZYME/LIPASE AMANO IME	0.010 kg.

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

Case No.	31 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008021AM24
RA File Number	522404000003 AM21
Licence No and Date	5210043427/09/06/2020

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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ETHERS, ALCOHOL PEROXIDES, ETHER PEROXIDES, KETONE PEROXIDES, EPOXIDES WITH A THREE- MEMBERED RING, ACETALS AND(HEMIACETALS AND THEIR HALOGENATED, SULPHONATED, NITRATED OR NITROSATED DERIVATIVES :AROMATIC ETHERS AND THEIR HALOGENATED, SULPHONATED, NITRATED OR NITROSATED DERIVATES : ANISOLE AND THEIR DERIVATIVES: 2-METHOXY-6-CHLOROTOLUENE.)	1 kg.	1	2,6 DICHLOROTOLUENE	1.42 kg.
		2	TETRAHYDROFURAN	0.64 kg.
		3	DIMETHYLSULFOXIDE	0.66 kg.

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

Case No.	32 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008025AM24
RA File Number	522404000017 AM21
Licence No and Date	5210043441/16/06/2020

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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
4-BROMOMETHYL-2-CYANOBI PHENYL	1 kg.	1	2-CHLOROBENZONITRILE	1.235 kg.
		2	PARA CHLOROTOLUENE	1.34 kg.

		3	TETRAHYDROFURAN	1.00 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	33 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008022AM24
RA File Number	522404000018 AM21
Licence No and Date	5210043446/23/06/2020

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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1-(2-(2-HYDROXYETHOXY) ETHYL) PIPERAZINE, CAS NO.13349-82-1	1 kg.	1	PIPERAZINE ANHYDROUS	1.00 kg.

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

Case No.	34 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	KusuMa PharMa
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007655AM24
RA File Number	039404000198 AM21
Licence No and Date	0310837494/29/07/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the written comments of Department of Chemicals & Petrochemicals vide their U.O. No.14010/32/2013-Ch.II dated 15/04/2015 and decision for same

export product/import product in meeting **No.1/82-ALC4/2015** dated **15/04/2015** against advance authorization **No.0310788806** dated **05/09/2014**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SODIUM SACCHARIN (PURE DENTAL GRADE)	1 kg.	1	SODIUM SACCHARIN	1.02 kg.

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

Case No.	35 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	KOSHA CHEMTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007382AM24
RA File Number	039404000306 AM21
Licence No and Date	0310837580/10/08/2020

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2 FORMYL BENZENE SULPHONIC ACID	1 kg.	1	SODIUM META BISULPHITE (SMBS)	0.893 kg.
		2	ORTHO CHLORO BENZALDEHYDE	0.90 kg.

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

Case No.	36 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	KusuMa PharMa
Meeting Number	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024

and Date											
HQ File Number	HQRNORM REVIW00007634AM24										
RA File Number	039404000356 AM21										
Licence No and Date	0310837963/28/08/2020										
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the written comments of Department of Chemicals & Petrochemicals vide their U.O. No.14010/32/2013-Ch.II dated 15/04/2015 and decision for same export product/import product in meeting No.1/82-ALC4/2015 dated 15/04/2015 against advance authorization No.0310788806 dated 05/09/2014, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>SODIUM SACCHARIN (PURE DENTAL GRADE)</td> <td>1 kg.</td> <td>1</td> <td>SODIUM SACCHARIN</td> <td>1.02 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. allowed.	SODIUM SACCHARIN (PURE DENTAL GRADE)	1 kg.	1	SODIUM SACCHARIN	1.02 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
SODIUM SACCHARIN (PURE DENTAL GRADE)	1 kg.	1	SODIUM SACCHARIN	1.02 kg.							

Case No.	37 / NC/3/MEET/Feb/202324/23													
Case Status	Case Approved													
Party Name	SRF LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024													
HQ File Number	HQRNORM REVIW00007267AM23													
RA File Number	052404000395 AM21													
Licence No and Date	0510415782/09/11/2020													
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 border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>DIFLUORO METHANE SULPHONYL CHLORIDE</td> <td>1 kg.</td> <td>1</td> <td>BENZYL DIFLUOROMETHYL SULPHIDE</td> <td>1.516 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DIFLUORO METHANE SULPHONYL CHLORIDE	1 kg.	1	BENZYL DIFLUOROMETHYL SULPHIDE	1.516 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
DIFLUORO METHANE SULPHONYL CHLORIDE	1 kg.	1	BENZYL DIFLUOROMETHYL SULPHIDE	1.516 kg.										

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

Case No.	38 / NC/3/MEET/Feb/202324/23
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007804AM24
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.	39 / NC/3/MEET/Feb/202324/23
Case Status	Case Rejected
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007805AM24
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.	40 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008364AM24
RA File Number	05AA04025954 AM21
Licence No and Date	0511001043/02/02/2021
Norms Committee Decision:	

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

Case No.	41 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006922AM24
RA File Number	31AA04006051 AM21
Licence No and Date	3111000148/09/02/2021

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/202324/13** dated **14/09/2023** against advance authorization **No. 3111000201 dated 08/03/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ETHYLENE DI AMINE (ORGANIC CHEMICAL)	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.	42 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	LARK LABORATORIES (INDIA) LTD
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008143AM24
RA File Number	05AA04036527 AM21
Licence No and Date	0511001512/02/03/2021

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/Mar/202324/24** dated **13/04/2023** against advance authorization **No. 0511007234 dated 25/06/2021**; it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SITAGLIPTIN TABLETS BP 100 MG (NET CONTENT SITAGLIPTIN PHOSPHATE MONOHYDRATE BP- 73.68 KGS) (EACH FILM COATED TABLET CONTAINS: SITAGLIPTIN PHOSPHATE MONOHYDRATE BP EQUIVALENT TO SITAGLIPTIN 100 MG)	1 Number	1	SITAGLIPTIN PHOSPHATE MONOHYDRATE BP	131.05 mg.

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

Case No.	43 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	ORIENTAL AROMATICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008140AM24
RA File Number	03AA04029725 AM21
Licence No and Date	0311002554/16/03/2021

Norms Committee Decision:

1. **Explain use of Aluminum Tri-2-Butoxide and DI N-Butyl Amine in chemical reaction and their end use.**
2. **Stoichiometric reaction indicate use of both raw material.**

Case No.	44 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005927AM24
RA File Number	NA
Licence No and Date	0911000512/18/03/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
RACTOPAMINE HCL (for Veterinary use))	1 kg	1	AMINO ACETONITRILE HCL	0.803 kg.
		2	4 HYDROXY BENZALDEHYDE	0.753 kg.

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

Case No.	45 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	REYAANSH HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007729AM24
RA File Number	03AA04021445 AM21
Licence No and Date	0311002623/19/03/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SELAMECTIN 6% SPOT ON 0.25 ML TUBE(EACH ML CONTAINS SELAMECTIN 60 MG)	11,000 Numbers	1	SELAMECTIN	168.305 gm.
SELAMECTIN 6% SPOT ON 0.50 ML TUBE(EACH ML CONTAINS SELAMECTIN 60 MG)	47,000 Numbers	2	SELAMECTIN	1438.153 gm.
SELAMECTIN 6% SPOT ON 0.75 ML TUBE(EACH ML CONTAINS SELAMECTIN 60 MG)	92000 Numbers	3	SELAMECTIN	4222.735 gm.
SELAMECTIN 6% SPOT ON 1 ML TUBE(EACH ML CONTAINS SELAMECTIN 60 MG)	50,000 Numbers	4	SELAMECTIN	3060.149 gm.

SELAMECTIN 6% SPOT ON 2 ML TUBE(EACH ML CONTAINS SELAMECTIN 60 MG)	30,000 Numbers	5	SELAMECTIN	3671.932 gm.
SELAMECTIN 6% SPOT ON 4 ML TUBE(EACH ML CONTAINS SELAMECTIN 60 MG)	2000 Numbers	6	SELAMECTIN	489.605 gm.

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

Case No.	46 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007375AM24
RA File Number	05AA04009888 AM22
Licence No and Date	0511002414/04/05/2021

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/Dec/202324/17** dated **20/12/2023** against advance authorization **No. 0511015244** dated **11/10/2022**, 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. allowed.
Buprenorphine Hydrochloride ((Bulk Drug/ Pharmacopeal Grade))	1 kg.	1	7(Alpha)-(2-Hydroxy-3,3-Dimethyl-2-Butyl)-6,14-Endo-Ethano-6,7,8,14-Tetrahydronorthebaine 20-t-butyl-dihydro-northevinol	1.955 kg.
		4	Cyclopropyl Methanol	1.60 kg.
		7	Mehtane Sulfonyl Chloride	2.50 kg.
		10	Lithium Bromide	2.00 kg.
		13	Thiophenol	2.50 kg.

		16	Dimethyl Formamide	4.00 kg.
		19	Triethyl Amine	4.80 kg.
		22	Toluene	20.50 kg.
		25	Methanol	5.50 kg.
		28	Activated Carbon / Eno Carbon	0.200 kg.
		31	Acetone	4.50 kg.
Buprenorphine Hydrochloride Tablets 2 Mg ((Each Tablets Contains 2mg Buprenorphine HCL) Bulk Drug Qty. 20.4 kg)	As per SION A-412			
Buprenorphine Hydrochloride Tablets 8 Mg((Each Tablets Contains 8mg Buprenorphine HCL) Bulk Drug Qty. 81.6 Kg.)	As per SION A-412			

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

Case No.	47 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	KusuMa PharMa
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007692AM24
RA File Number	03AA04009329 AM22
Licence No and Date	0311003661/08/05/2021
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the written comments of Department of Chemicals & Petrochemicals vide their U.O. No.14010/32/2013-Ch.II dated 15/04/2015 and decision for same export product/import product in meeting No.1/82-ALC4/2015 dated 15/04/2015 against advance authorization No.0310788806 dated 05/09/2014, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SODIUM SACCHARIN (PURE DENTAL GRADE)	1 kg.	1	SODIUM SACCHARIN	1.02 kg.

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

Case No.	48 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007661AM24
RA File Number	34AA04004352 AM22
Licence No and Date	3411000801/06/07/2021

Norms Committee Decision:

The Committee considered the case as per agenda and 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.3410046524 dated 05/11/2020**, 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. allowed.
Gamma Nonalactone (Aldehyde C18)	1 kg.	1	N-Hexanol	1.36 kg.

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

Case No.	49 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007920AM24
RA File Number	05AA04070230 AM22

Licence No and Date	0511004557/06/09/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	50 / NC/3/MEET/Feb/202324/23																						
Case Status	Case Approved																						
Party Name	SRF LIMITED																						
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024																						
HQ File Number	HQRNORM REVIW00007959AM24																						
RA File Number	05AA04076110 AM22																						
Licence No and Date	0511004515/06/09/2021																						
Norms Committee Decision:																							
The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																							
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="4">HFC-134a (HYDROFLUOROCARBAN 1,1,1,2-TETRAFLUOROETHANE)</td><td rowspan="4">1kg</td><td>1</td><td>ETHYLENE DI CHLORIDE</td><td>1.105kg.</td></tr><tr><td>2</td><td>ACID GRADE FLUORSPAR</td><td>2.121 kg.</td></tr><tr><td>3</td><td>EMPTY CANS SUPERTECH 340G</td><td>Relevant as per packing policy</td></tr><tr><td>4</td><td>CAPS FOR EMPTY CANS / TINPLATE CAP 1/2 Inch</td><td>Relevant as per packing policy</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	HFC-134a (HYDROFLUOROCARBAN 1,1,1,2-TETRAFLUOROETHANE)	1kg	1	ETHYLENE DI CHLORIDE	1.105kg.	2	ACID GRADE FLUORSPAR	2.121 kg.	3	EMPTY CANS SUPERTECH 340G	Relevant as per packing policy	4	CAPS FOR EMPTY CANS / TINPLATE CAP 1/2 Inch	Relevant as per packing policy
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																			
HFC-134a (HYDROFLUOROCARBAN 1,1,1,2-TETRAFLUOROETHANE)	1kg	1	ETHYLENE DI CHLORIDE	1.105kg.																			
		2	ACID GRADE FLUORSPAR	2.121 kg.																			
		3	EMPTY CANS SUPERTECH 340G	Relevant as per packing policy																			
		4	CAPS FOR EMPTY CANS / TINPLATE CAP 1/2 Inch	Relevant as per packing policy																			
RA concerned may take further necessary action as per above decision of NC.																							

Case No.	51 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008056AM24

RA File Number	05AA04076999 AM22
Licence No and Date	0511004742/15/09/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	52 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008200AM24
RA File Number	05AA040108247 AM22
Licence No and Date	0511006681/07/12/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	53 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008265AM24
RA File Number	05AX04000189 AM22
Licence No and Date	0511007079/21/12/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	54 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006821AM24
RA File Number	038504000145 AM21
Licence No and Date	0311010587/17/01/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	55 / NC/3/MEET/Feb/202324/23										
Case Status	Case Approved										
Party Name	KusuMa PharMa										
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024										
HQ File Number	HQRNORM REVIW00006625AM24										
RA File Number	03AX04001369 AM22										
Licence No and Date	0311011710/23/02/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the written comments of Department of Chemicals & Petrochemicals vide their U.O. No.14010/32/2013-Ch.II dated 15/04/2015 and decision for same export product/import product in meeting No.1/82-ALC4/2015 dated 15/04/2015 against advance authorization No.0310788806 dated 05/09/2014, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>SODIUM SACCHARIN (PURE DENTAL GRADE)</td><td>1 kg.</td><td>1</td><td>SODIUM SACCHARIN</td><td>1.02 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	SODIUM SACCHARIN (PURE DENTAL GRADE)	1 kg.	1	SODIUM SACCHARIN	1.02 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
SODIUM SACCHARIN (PURE DENTAL GRADE)	1 kg.	1	SODIUM SACCHARIN	1.02 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	56 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	KusuMa PharMa
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007433AM24
RA File Number	03AX04001369 AM22
Licence No and Date	0311011710/23/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the written comments of Department of Chemicals & Petrochemicals vide their U.O. No.14010/32/2013-Ch.II dated 15/04/2015 and decision for same export product/import product in meeting No.1/82-ALC4/2015 dated 15/04/2015 against advance authorization No.0310788806 dated 05/09/2014, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SODIUM SACCHARIN (PURE DENTAL GRADE)	1 kg.	1	SODIUM SACCHARIN	1.02 kg.

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

Case No.	57 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006822AM24
RA File Number	03AX04000957 AM22
Licence No and Date	0311011997/28/02/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	58 / NC/3/MEET/Feb/202324/23			
Case Status	Case Approved			
Party Name	AARTI DRUGS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024			
HQ File Number	HQRNORM REVIW00008294AM24			
RA File Number	03AX04001604 AM22			
Licence No and Date	0311013055/17/03/2022			
Norms Committee Decision:				
As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses:				
The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

Ciprofloxacin Hydrochloride BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.
		2	Piperazine Anhydrous	0.390 kg.

Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis of these norms.

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

Case No.	59 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008340AM24
RA File Number	03AX04001595 AM22
Licence No and Date	0311013059/17/03/2022

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses:

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ciprofloxacin Hydrochloride BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.
		2	Piperazine Anhydrous	0.390 kg.

Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis

of these norms.

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

Case No.	60 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008341AM24
RA File Number	03AX04001592 AM22
Licence No and Date	0311013060/17/03/2022

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses:

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ciprofloxacin Hydrochloride BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.
		2	Piperazine Anhydrous	0.390 kg.

Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis of these norms.

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

Case No.	61 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024																
HQ File Number	HQRNORM REVIW00008342AM24																
RA File Number	03AX04001843 AM22																
Licence No and Date	0311013348/25/03/2022																
Norms Committee Decision: As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses: The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:- <table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Ciprofloxacin Hydrochloride BP/EP/USP</td> <td rowspan="2">1 kg.</td> <td>1</td> <td>Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate</td> <td>1.294 kg.</td> </tr> <tr> <td>2</td> <td>Piperazine Anhydrous</td> <td>0.390 kg.</td> </tr> </tbody> </table> Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis of these norms. RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Ciprofloxacin Hydrochloride BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.	2	Piperazine Anhydrous	0.390 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Ciprofloxacin Hydrochloride BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.													
		2	Piperazine Anhydrous	0.390 kg.													

Case No.	62 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008343AM24
RA File Number	03AX04001856 AM22
Licence No and Date	0311013341/25/03/2022
Norms Committee Decision: As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar	

Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses:

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ciprofloxacin Hydrochloride BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.
		2	Piperazine Anhydrous	0.390 kg.

Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis of these norms.

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

Case No.	63 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008344AM24
RA File Number	03AX04001844 AM22
Licence No and Date	0311013405/28/03/2022

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses:

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Ciprofloxacin Hydrochloride BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.
		2	Piperazine Anhydrous	0.390 kg.

Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis of these norms.

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

Case No.	64 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006448AM24
RA File Number	03AX04000062 AM23
Licence No and Date	0311013759/11/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Mar/202122/16 dated 08/04/2022** against advance authorization **No.0311008243** dated **03/11/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DIPHENYL ISODECYL PHOSPHITE ((DPDP))	1 kg.	1	PHENOL	0.557 kg.
		2	ISODECYL ALCOHOL OR 2 PROPYL HEPTANOL	0.419 kg.
		3	YELLOW PHOSPHORUS	0.087 kg.

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

Case No.	65 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008345AM24
RA File Number	03AX04000017 AM23
Licence No and Date	0311013787/11/04/2022

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses:

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ciprofloxacin Hydrochloride BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.
		2	Piperazine Anhydrous	0.390 kg.

Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis of these norms.

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

Case No.	66 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008363AM24
RA File Number	03AX04000191 AM23
Licence No and Date	0311014067/22/04/2022

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses:

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ciprofloxacin Hydrochloride - USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.
		2	Piperazine Anhydrous	0.390 kg.

Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis of these norms.

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

Case No.	67 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008346AM24
RA File Number	03AX04000196 AM23
Licence No and Date	0311014132/25/04/2022

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses:

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ciprofloxacin Hydrochloride	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.
		2	Piperazine Anhydrous	0.390 kg.

Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis of these norms.

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

Case No.	68 / NC/3/MEET/Feb/202324/23
Case Status	Case Rejected
Party Name	KOSHA CHEMTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007455AM24
RA File Number	03AX04000276 AM23
Licence No and Date	0311014758/17/05/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case.	

Case No.	69 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008347AM24
RA File Number	03AX04000640 AM23
Licence No and Date	0311014736/17/05/2022
Norms Committee Decision:	
As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar	

Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses:

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ciprofloxacin Hydrochloride IP/BP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.
		2	Piperazine Anhydrous	0.390 kg.

Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis of these norms.

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

Case No.	70 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008348AM24
RA File Number	03AX04000697 AM23
Licence No and Date	0311014994/25/05/2022

Norms Committee Decision:

As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses:

The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Ciprofloxacin Hydrochloride BP/EP/USP	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.
		2	Piperazine Anhydrous	0.390 kg.

Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis of these norms.

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

Case No.	71 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00000608AM24
RA File Number	05AX04000553 AM23
Licence No and Date	0511012820/26/05/2022

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. allowed.
HFC-134a (HYDROFLUOROCARBAN) 1,1,1,2-TETRAFLUOROETHANE)	1kg	1	ETHYLENE DI CHLORIDE	1.105kg.
		2	ACID GRADE FLUORSPAR	2.121 kg.
		3	EMPTY CANS (340 GRAM)	Relevant as per packing policy
		4	CAPS FOR EMPTY CANS/ TINPLATE VALVE 1/2"	Relevant as per packing policy

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

Case No.	72 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00004512AM24
RA File Number	03AX04000506 AM23
Licence No and Date	0311015097/30/05/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRIACETIN	1 kg.	1	ISOBUTYL ACETATE	Indigenously source
		2	REFINED GLYCERINE (GLYCEROL)	0.444 kg.
		3	ACETIC ACID	0.74 kg.
		4	ACETIC ANHYDRIDE	0.06 kg.
		5	MARLON AS 3	Indigenously source

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

Case No.	73 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008349AM24
RA File Number	03AX04000874 AM23
Licence No and	0311015096/30/05/2022

Date				
Norms Committee Decision:				
As per the decision taken by the Committee in its Meeting No. NC/3/MEET/Nov/202223/13 dated 24/11/2022, the factory visit of M/s Aarti Drugs Limited was carried out on 04/02/2023 under the Chairmanship of Shri Rajiv Kumar Soni, Joint DGFT to ascertain the exact wastage of import items in their licenses:				
The Committee examined the Factory Visit Report and after deliberation, it was decided to revise ad-hoc norms as under:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Ciprofloxacin HCL	1 kg.	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.294 kg.
		2	Piperazine Anhydrous	0.390 kg.
Note: The above norms are only for regularization purpose and no repeat license will be issued on the basis of these norms.				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	74 / NC/3/MEET/Feb/202324/23			
Case Status	Case Approved			
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024			
HQ File Number	HQRNORM REVIW00007230AM24			
RA File Number	31AX04000064 AM23			
Licence No and Date	3111001476/24/06/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Sep/202324/13 dated 14/09/2023 against advance authorization No. 3111000201 dated 08/03/2021, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.

ETHYLENE DI AMINE (ORGANIC CHEMICAL)	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.	75 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006037AM24
RA File Number	NA
Licence No and Date	0711004432/28/06/2022

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/Nov/202223/12 dated 18/11/2022** against advance authorization **No.0711003901 dated 19/05/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cyanocobala min inj. 1mL(2mL Vial - filled with 1mg of Cyanocobalamin as bulk drug mixed in water for injection and filled in 2mL Vial and capped with 13mm chlorobutyle Rubber Stopper)	681818.18 Numbers	1	V-35 4432/50/GREY Westar? RS SIL 1 (13mm Chlorobutyl R/S V-35 4432/50 Grey - RFS)	Relevant, as per Packing Policy
Furosemide Injection 10mg/mL - 4mL Vial(4mL Vial - filled with 40mg of furosemide as bulk drug mixed in water for injection and filled in 4mL Vial and capped with 13mm chlorobutyle Rubber Stopper)	1863636.36 Numbers	2	V-35 4432/50/GREY Westar? RS SIL 1 (13mm Chlorobutyl R/S V-35 4432/50 Grey - RFS)	Relevant, as per Packing Policy
Prochlorperazine Edisylate Injection USP 10mg/2mL(2mL Vial - Prochlorperazine Edisylate Injection USP 10mg/2mL and capped with 13mm	181818.18 Numbers	3	V-35 4432/50/GREY Westar? RS SIL 1 (13mm Chlorobutyl R/S V-35 4432/50 Grey - RFS)	Relevant, as per Packing Policy

chlorobutyle Rubber Stopper)				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	76 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006557AM24
RA File Number	NA
Licence No and Date	0711004447/28/06/2022

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/Dec/202223/15 dated 29/12/2022** against advance authorization **No.0711004447** dated **28/06/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Sodium Bicarbonate Injection 84mg/mL - 50mL Vial(Sodium Bicarbonate as bulk drug filled in 50mL Vial and capped with 20mm Bromobutyl Grey Rubber Stopper)	363636.0 Numbers	1	S-127 4432/50/Grey Westar RS SIL 1 (20mm Grey Chlorobutyl Rubber Stopper-RFS)	Relevant, as per packing policy
Sodium Bicarbonate Injection 84mg/mL - 50mL Vial (Sodium Bicarbonate Injection 84mg/mL -50mL Vial)	90909.0 Numbers	2	S-127 4432/50/Grey Westar RS SIL 1 (20mm Grey Chlorobutyl Rubber Stopper-RFS)	Relevant, as per packing policy

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

Case No.	77 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024

HQ File Number	HQRNORM REVIW00007086AM24													
RA File Number	31AX04000054 AM23													
Licence No and Date	3111001493/04/07/2022													
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/Sep/202324/13 dated 14/09/2023 against advance authorization No. 3111000201 dated 08/03/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">ETHYLENE DI AMINE (ORGANIC CHEMICAL)</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. allowed.	ETHYLENE DI AMINE (ORGANIC CHEMICAL)	1 kg	1	MONOETHANOLAMINE	1.06 kg.	2	AMMONIA ANHYDROUS	0.294 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
ETHYLENE DI AMINE (ORGANIC CHEMICAL)	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.	78 / NC/3/MEET/Feb/202324/23
Case Status	Case Rejected
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007981AM24
RA File Number	03AX04001943 AM23
Licence No and Date	0311016208/08/07/2022
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.	79 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	APEX DRUG HOUSE
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007290AM24
RA File Number	03AX04002053 AM23
Licence No and Date	0311016315/13/07/2022

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. allowed.
Benzocaine & Dequalinium Chloride Lozenges (Benzocaine Dequalinium Chloride Lozenges (ELIDOL DUO (Raspberry Flavour) Each Lozenge contains Benzocaine BP 10 mg, Dequalinium Chloride 0.25 mg Net Content: 1) Dequalinium Chloride BP - 518.518 GRAMS 2) Benzocaine BP - Kgs (Indigenous): 31.111 KGS)	2074072 Numbers	1	Dequalinium Chloride BP	528.90 gm.

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

Case No.	80 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	STYRAX LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00002187AM23
RA File Number	09AX04000313 AM23
Licence No and Date	0911003379/21/07/2022

Norms Committee Decision:

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

Get the Advance Authorisation amended to show actual export item.

Case No.	81 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	CANPEX CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007146AM24
RA File Number	31AX04000115 AM23

Licence No and Date	3111001583/22/07/2022			
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/Jan/202324/13 dated 18/01/2024 against advance authorization No. 3111002080 dated 10/03/2023, 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. allowed.
CYANAMIDE 50% SOLUTION	1 kg.	1	CALCIUM CYANAMIDE (Purity 63% as per CoA)	1.913 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	82 / NC/3/MEET/Feb/202324/23			
Case Status	Case Approved			
Party Name	ASCENT FINECHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024			
HQ File Number	HQRNORM REVIW00006819AM24			
RA File Number	08AX04000679 AM23			
Licence No and Date	0811005628/26/07/2022			
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/Dec/202324/17 dated 20/12/2023 against advance authorization No.0811001850 dated 25/06/2021; it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Indoline	1 kg.	1	O-CHLOROBENZYL CYANIDE	2.20 kg.
		2	TOLUENE	1.00 kg.

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

Case No.	83 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	MACLEODS PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008151AM24
RA File Number	03AX04002952 AM23
Licence No and Date	0311017587/08/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant documents from the firm.	

Case No.	84 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008055AM24
RA File Number	05AX04001704 AM23
Licence No and Date	0511014859/16/09/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	85 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00003901AM23
RA File Number	03AX04003806 AM23
Licence No and Date	0311018798/22/10/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRIS NONYL PHENYL PHOSPHITE((TNPP))	1 kg.	1	NONYL PHENOL	1.066 kg.
		2	YELLOW PHOSPHORUS	0.0506 kg.

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

Case No.	86 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00003910AM23
RA File Number	30AX04000299 AM23
Licence No and Date	3011002731/25/10/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	87 / NC/3/MEET/Feb/202324/23										
Case Status	Case Approved										
Party Name	SUNSHIELD CHEMICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024										
HQ File Number	HQRNORM APPLY 00003993AM23										
RA File Number	03AX04003805 AM23										
Licence No and Date	0311018972/01/11/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>SDPA</td><td>1 kg.</td><td>1</td><td>DI-PHENYLAMINE</td><td>0.470 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	SDPA	1 kg.	1	DI-PHENYLAMINE	0.470 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
SDPA	1 kg.	1	DI-PHENYLAMINE	0.470 kg.							

(STYRENATED DI-PHENYLAMINE)		2	STYRENE MONOMER	0.529 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	88 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007919AM24
RA File Number	05AX04002217 AM23
Licence No and Date	0511015715/09/11/2022
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	89 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008380AM24
RA File Number	09AX04000689 AM23
Licence No and Date	0911003913/09/11/2022
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
1. Percentage yield at every stage of reaction.	

Case No.	90 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007116AM24
RA File Number	31AX04000250 AM23
Licence No and Date	3111001849/29/11/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Sep/202324/13** dated **14/09/2023** against advance authorization **No. 3111000201** dated **08/03/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ETHYLENE DI AMINE (ORGANIC CHEMICAL)	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.	91 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007528AM24
RA File Number	34AX04000871 AM23
Licence No and Date	3411003177/23/12/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jan/202324/21** dated **24/01/2024** against advance authorization **No. 3411003731** dated **18/05/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Undecavertol (Kakdinol)((4-Methyl-3-decen- 5-ol))	1 kg.	1	Propionaldehyde	0.947 kg.
		2	1-Pentanol / N Amyl Alcohol	0.709 kg.
		3	Magnesium Turning	0.182 kg.

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

Case No.	92 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	MACLEODS PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008388AM24
RA File Number	03AX04004899 AM23
Licence No and Date	0311020446/03/01/2023
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 along with relevant documents from the firm.	

Case No.	93 / NC/3/MEET/Feb/202324/23															
Case Status	Case Approved															
Party Name	MAIVA PHARMA PRIVATE LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024															
HQ File Number	HQRNORM APPLY 00006560AM24															
RA File Number	NA															
Licence No and Date	0711006109/06/01/2023															
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.0711006109 dated 06/01/2023 , 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:-																
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Rocuronium Bromide Injection 5mg/ml - 5mL Vial(Rocuroniu m Bromide Injection 5mg/ml - 5mL Vial)</td><td>318182.0 Numbers</td><td>1</td><td>S-127 4432/50/GREY Westar? RS SIL 1 (20mm Grey Chlorobutyl Rubber Stopper - RFS)</td><td>Relevant, as per packing policy</td></tr><tr><td>Rocuronium Bromide Injection 5mg/ml - 5mL Vial (Rocuronium</td><td>227273.0 Numbers</td><td>2</td><td>S-127 4432/50/GREY Westar? RS SIL 1 (20mm</td><td>Relevant, as per packing policy</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Rocuronium Bromide Injection 5mg/ml - 5mL Vial(Rocuroniu m Bromide Injection 5mg/ml - 5mL Vial)	318182.0 Numbers	1	S-127 4432/50/GREY Westar? RS SIL 1 (20mm Grey Chlorobutyl Rubber Stopper - RFS)	Relevant, as per packing policy	Rocuronium Bromide Injection 5mg/ml - 5mL Vial (Rocuronium	227273.0 Numbers	2	S-127 4432/50/GREY Westar? RS SIL 1 (20mm	Relevant, as per packing policy
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Rocuronium Bromide Injection 5mg/ml - 5mL Vial(Rocuroniu m Bromide Injection 5mg/ml - 5mL Vial)	318182.0 Numbers	1	S-127 4432/50/GREY Westar? RS SIL 1 (20mm Grey Chlorobutyl Rubber Stopper - RFS)	Relevant, as per packing policy												
Rocuronium Bromide Injection 5mg/ml - 5mL Vial (Rocuronium	227273.0 Numbers	2	S-127 4432/50/GREY Westar? RS SIL 1 (20mm	Relevant, as per packing policy												

Bromide Injection 5mg/ml-5mL Vial - Filled with 50mg of Rocuronium Bromide USP 10 mg as bulk drug filled in 5mL vial and capped with 20mm Bromobutyl Grey Rubber Stopper)			Grey Chlorobutyl Rubber Stopper - RFS)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	94 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	MACLEODS PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008389AM24
RA File Number	03AX04005022 AM23
Licence No and Date	0311020561/09/01/2023
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 along with relevant documents from the firm.	

Case No.	95 / NC/3/MEET/Feb/202324/23																			
Case Status	Case Approved																			
Party Name	SALICYLATES & CHEMICALS PRIVATE LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024																			
HQ File Number	HQRNORM APPLY 00006995AM23																			
RA File Number	NA																			
Licence No and Date	0911004487/17/02/2023																			
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><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>SALISOL HS (PBSA) / Ensulizole (2-Phenylbenzimidazole-5- sulfonic acid)</td><td>1 kg.</td><td>1</td><td>ORTHO PHENYLENEDIAMINE</td><td>0.55 kg.</td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	SALISOL HS (PBSA) / Ensulizole (2-Phenylbenzimidazole-5- sulfonic acid)	1 kg.	1	ORTHO PHENYLENEDIAMINE	0.55 kg.					
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
SALISOL HS (PBSA) / Ensulizole (2-Phenylbenzimidazole-5- sulfonic acid)	1 kg.	1	ORTHO PHENYLENEDIAMINE	0.55 kg.																

		2	BENZALDEHYDE	0.545 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	96 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	MACLEODS PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00008390AM24
RA File Number	03AX04005710 AM23
Licence No and Date	0311021583/24/02/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case along with relevant documents from the firm.	

Case No.	97 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006563AM24
RA File Number	08AX04001977 AM23
Licence No and Date	0811007532/10/03/2023
Norms Committee Decision:	
The committee considered the request of firm for review/fixation of ad-hoc norms and it was decided to call for following information/documents from the firm:-	
i. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. ii. Justification for requirement of raw material.	

Case No.	98 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	KusuMa PharMa
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007449AM24
RA File Number	03AX04005815 AM23

Licence No and Date	0311022080/11/03/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the written comments of Department of Chemicals & Petrochemicals vide their U.O. No.14010/32/2013-Ch.II dated 15/04/2015 and decision for same export product/import product in meeting No.1/82-ALC4/2015 dated 15/04/2015 against advance authorization No.0310788806 dated 05/09/2014 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>SODIUM SACCHARIN (PURE DENTAL GRADE)</td><td>1 kg.</td><td>1</td><td>SODIUM SACCHARIN</td><td>1.02 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	SODIUM SACCHARIN (PURE DENTAL GRADE)	1 kg.	1	SODIUM SACCHARIN	1.02 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
SODIUM SACCHARIN (PURE DENTAL GRADE)	1 kg.	1	SODIUM SACCHARIN	1.02 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	99 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006561AM24
RA File Number	04AX04001126 AM23
Licence No and Date	0411005084/21/03/2023
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and it was decided to call for following information/documents from the firm:- i. Get the Advance Authorisation amended with correct description of export and import product from concerned RA.	

Case No.	100 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	ABBOTT HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00007548AM24
RA File Number	03AX04001130 AM24
Licence No and Date	0311024614/16/06/2023

Norms Committee Decision:

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

Case No.	101 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AROHEMA INGREDIENTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006496AM24
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/Dec/202324/17 dated 20/12/2023** against advance authorization **No. 2611000716** dated **23/09/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ORCANOX	1 kg.	1	SCLAREOL	2.0458 kg.
		2	TRET AMYL ALCOHOL	2.64 kg.

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

Case No.	102 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006559AM24
RA File Number	04AX04000303 AM24
Licence No and Date	0411005642/04/07/2023

Norms Committee Decision:

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

Get the Advance Authorisation amended with correct description of export and import product from concerned RA.

Case No.	103 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AROHEMA INGREDIENTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM REVIW00006497AM24
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/Dec/202324/17 dated 20/12/2023** against advance authorization **No. 2611000716** dated **23/09/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ORCANOX	1 kg.	1	SCLAREOL	2.0458 kg.
		2	TRET AMYL ALCOHOL	2.64 kg.

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

Case No.	104 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	NAPROD LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005757AM24
RA File Number	03AX04002815 AM24
Licence No and Date	0311027227/20/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Vecuronium Bromide For Injection BP 10mg	156863.0 Numbers	1	Vecuronium Bromide Ph EUR	1600.0 gm.

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

Case No.	105 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005761AM24
RA File Number	09AX04000551 AM24
Licence No and Date	0911005810/20/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CARBIDOPA 12.5MG LEVODOPA 50MG TABLETS(CARBIDOPA 12.5MG LEVODOPA 50MG TABLETS)	1 Number	1	CARBIDOPA	12.75 mg.
		2	LEVODOPA	51.00 mg.
CARBIDOPA 10MG LEVODOPA 100MG TABLETS(CARBIDOPA 10MG LEVODOPA 100MG TABLETS)	1 Number	3	CARBIDOPA	10.2 mg.
		4	LEVODOPA	102.00 mg.
CARBIDOPA 25MG LEVODOPA 100MG TABLETS(CARBIDOPA 25MG LEVODOPA 100MG TABLETS)	1 Number	5	CARBIDOPA	25.50 mg.
		6	LEVODOPA	102.00 mg.
CARBIDOPA 25MG LEVODOPA 250MG	1 Number	7	CARBIDOPA	25.50 mg.

TABLETS(CARBIDOPA 25MG LEVODOPA 250MG TABLETS)		8	LEVODOPA	255.00 mg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	106 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005769AM24
RA File Number	03AX04002843 AM24
Licence No and Date	0311027245/20/09/2023

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 **HQ. File No. HQRNORMAPPLY00000449AM24**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
SULFADOXINE	1 kg.	1	4,6 Dichloro 5-Methoxy Pyrimidine (DCMP)	0.78 kg.
		2	SULFANILAMIDE	0.90 kg.

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

Case No.	107 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005776AM24
RA File Number	03AX04002663 AM24
Licence No and Date	0311027253/21/09/2023
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 along with relevant documents from the firm.

Case No.	108 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005777AM24
RA File Number	03AX04002664 AM24
Licence No and Date	0311027255/21/09/2023

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 along with relevant documents from the firm.

Case No.	109 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005779AM24
RA File Number	34AX04000492 AM24
Licence No and Date	3411004138/21/09/2023

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/202223/24 dated 13/04/2023** against advance authorization **No.3411002060 dated 31/03/2022**, 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:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Duloxetine Caps.20 mg (Net content of active ingredients 180.000 kgs)	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	22.88 mg.
		2	Sugar Spheres (30-35 PHARM-A-SPHERES)	20.33 mg.
		3	Hypromellose (Pharmacoat 606)	20.00 mg.

		4	Talc (Luzenac Pharma Ultra Micronised grade)	12.63 mg.
		5	Sucrose (Compressuc PS)	50.67 mg.
		6	Hypromellose Phthalate (HP 55)	12.07 mg.
		7	Triethyl Citrate	1.21 mg.
Duloxetine Caps. 30 mg (Net content of active ingredients 750.00 kgs)	1 Number Capsule	8	Duloxetine Hydrochloride Ph,Eur.	34.36 mg.
		9	Sugar Spheres (30-35 PHARM-A-SPHERES)	30.50 mg.
		10	Hypromellose (Pharmacoat 606)	30.00 mg.
		11	Talc (Luzenac Pharma Ultra Micronised grade)	18.94 mg.
		12	Sucrose (Compressuc PS)	23.50 mg.
		13	Hypromellose Phthalate (HP 55)	18.10 mg.
		14	Triethyl Citrate	1.81 mg.
Duloxetine Caps. 40 mg (Net content of active ingredients 360.000 kgs))	1 Number Capsule	15	Duloxetine Hydrochloride Ph,Eur.	45.76 mg.
		16	Sugar Spheres (30-35 PHARM-A-SPHERES)	40.67 mg.
		17	Hypromellose (Pharmacoat 606)	40.00 mg.
		18	Talc (Luzenac Pharma Ultra Micronised grade)	25.26 mg.
		19	Sucrose (Compressuc PS)	31.34 mg.
		20	Hypromellose Phthalate (HP 55)	24.14 mg.

		21	Triethyl Citrate	2.41 mg.
Duloxetine Caps. 60 mg (Net content of active ingredients 1500.00 kgs))	1 Number Capsule	22	Duloxetine Hydrochloride Ph,Eur.	68.71 mg.
		23	Sugar Spheres (30-35 PHARM-A-SPHERES)	61.00 mg.
		24	Hypromellose (Pharmacoat 606)	60.00 mg.
		25	Talc (Luzenac Pharma Ultra Micronised grade)	37.88 mg.
		26	Sucrose (Compressuc PS)	47.00 mg.
		27	Hypromellose Phthalate (HP 55)	36.20 mg.
		28	Triethyl Citrate	3.62 mg.

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

Case No.	110 / NC/3/MEET/Feb/202324/23			
Case Status	Case Approved			
Party Name	ALEMBIC PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024			
HQ File Number	HQRNORM APPLY 00005780AM24			
RA File Number	34AX04000484 AM24			
Licence No and Date	3411004140/21/09/2023			
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/202223/24 dated 13/04/2023 against advance authorization No.3411001942 dated 10/03/2022 , 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:-				

Amantadine Hydrochloride capsules USP 100mg (Net content of active ingredients 400.00 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 800.00 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.	111 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005781AM24
RA File Number	34AX04000490 AM24
Licence No and Date	3411004141/21/09/2023

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/Sep/202324/14 dated 27/09/2023** against advance authorization **No. 3411003964 dated 31/07/2023**, 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. allowed.
Acetone	250 MT	1	Cumene	130.807 MT

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

Case No.	112 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005790AM24
RA File Number	03AX04002744 AM24
Licence No and Date	0311027270/21/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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METHYL SALICYLATE	1 kg.	1	SALICYLIC ACID	0.955 kg.
		2	METHANOL	0.244 kg.

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

Case No.	113 / NC/3/MEET/Feb/202324/23										
Case Status	Case Approved										
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024										
HQ File Number	HQRNORM APPLY 00005792AM24										
RA File Number	03AX04002721 AM24										
Licence No and Date	0311027272/21/09/2023										
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/202324/20 dated 18/01/2024 against advance authorization No.0311015523 dated 15/06/2022 , 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><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>TETRAHYDROFURAN (PURITY 99%)</td><td>1 kg</td><td>1</td><td>1,4 Butandiol (Purity Min. 95%)</td><td>1.42 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	TETRAHYDROFURAN (PURITY 99%)	1 kg	1	1,4 Butandiol (Purity Min. 95%)	1.42 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
TETRAHYDROFURAN (PURITY 99%)	1 kg	1	1,4 Butandiol (Purity Min. 95%)	1.42 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	114 / NC/3/MEET/Feb/202324/23			
Case Status	Case Deferred			
Party Name	AMI LIFESCIENCES PVT LTD			
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024			
HQ File Number	HQRNORM APPLY 00005805AM24			
RA File Number	34AX04000495 AM24			
Licence No and Date	3411004147/21/09/2023			

Norms Committee Decision:

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

Case No.	115 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005819AM24
RA File Number	07AX04000889 AM24
Licence No and Date	0711009270/22/09/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Jan/202223/18 dated 23/01/2023** against advance authorization **No. 0711001565 dated 27/07/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DOXYLAMINE SUCCINATE (USP/EP)	1 kg.	1	2 ACETYL PYRIDINE	0.58 kg.
		2	TETRA HYDRO FURAN	1.03 kg.
		3	TOLUENE	1.10 kg.
		4	ACETONE	0.83 kg.

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

Case No.	116 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005822AM24
RA File Number	03AX04002768 AM24
Licence No and Date	0311027333/22/09/2023

Norms Committee Decision:

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

Case No.	117 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005827AM24
RA File Number	03AX04002825 AM24
Licence No and Date	0311027340/22/09/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Dec/202324/19 dated 05/01/2024** against advance authorization **No. 0311019730 dated 02/12/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CHLORAMPHENICOL EYE DROPS 10 ML((EACH VIAL CONTAINS CHLORAMPHENICOL MICRONIZED 0.050GM NET WT OF BULK DRUG IS 32.750 KGS))	655000.0 Numbers	1	CHLORAMPHENICOL MICRONIZED	33.40 kg.

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

Case No.	118 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005845AM24
RA File Number	05AX04001599 AM24
Licence No and Date	0511021137/25/09/2023

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:-

CoA of export product and import item from foreign supplier.

Case No.	119 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005876AM24
RA File Number	08AX04001183 AM24
Licence No and Date	0811009470/26/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
NICARDIPINE HYDROCHLORIDE INJECTION 10mg/10ml USP/BP/IP/CEP/EP/ChP	1 Number	1	NICARDIPINE HCL	10.65 mg. / vial

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

Case No.	120 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005880AM24
RA File Number	08AX04001204 AM24
Licence No and Date	0811009475/26/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Calcium Chloride USP, 10% (10ML)	195650.0 Vials	1	Calcium chloride dihydrate	215.215 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	121 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	VANCE AND HEALTH PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005881AM24
RA File Number	05AX04001574 AM24
Licence No and Date	0511021173/26/09/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No. 0511018258** dated **12/04/2023**, 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. allowed.
Azithromycin Tablets 500mg (AZVAN-500 TABS)	1 Number	1	Azithromycin Dihydrate	534.54 mg./Tablet

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

Case No.	122 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005896AM24
RA File Number	03AX04002920 AM24
Licence No and Date	0311027458/27/09/2023

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. Stoichiometric balance with molar weight and to arrive at the quantity of raw material asked.**
- 2. Justification for 44% yield.**
- 3. Production/Consumption data certified by GST.**

Case No.	123 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	RUMIT LIFE CARE
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005898AM24
RA File Number	03AX04002915 AM24
Licence No and Date	0311027464/27/09/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Clobetasol Propionate IP/BP/EP/USP	1 kg.	1	Betamethasone IP/BP/EP/USP	1.00 kg.

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

Case No.	124 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005902AM24
RA File Number	07AX04000839 AM24
Licence No and Date	0711009310/27/09/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Feb/202223/20 dated 24/02/2023** against advance authorization

No. 0711005403 dated 03/10/2022, 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. allowed.
AMITRIPTYLINE HYDROCHLORIDE (IP/BP/EP/USP)	1 kg.	1	1 BROMO 3 CHLORO PROPANE	0.720 kg.
		2	TETRA HYDRO FURAN	0.530 kg.
		3	SODIUM BOROHYDRIDE	Not allowed as not shown in the process reaction.
		4	ACETONE	
		5	METHANOL	
		6	TOLUENE	

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

Case No.	125 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005907AM24
RA File Number	07AX04000981 AM24
Licence No and Date	0711009320/27/09/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Jun/202122/2 dated 02/07/2021** against advance authorization **No. 0711000843 dated 06/04/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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ACURATE TABLETS ((Paracetamol 450mg + Doxylamine Succinate 5mg + Caffeine 30mg + Codeine Phosphate 10mg + Color Quinoline Yellow 2Mg) (Para - 22500.000 + Doxy- 250.000+Caffeine-1500.000 + Codeine-500.000+Colour- 100.000Kgs) Total KGS- 24850.000 (No. of Tablets - 50000000))	50000000 Numbers	1	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	255.0 kg.
		2	CAFFEINE BP/Ph. Eur	1530.0 kg.
		3	CODEINE PHOSPHATE BP/USP/EP/PH.EUR	510.0 kg.
		4	COLOUR QUINOLINE YELLOW CI 47005 (SPECTRACOL)	100.0 kg.

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

Case No.	126 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005917AM24
RA File Number	07AX04000983 AM24
Licence No and Date	0711009327/27/09/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Jun/202122/2 dated 02/07/2021** against advance authorization **No. 0711000843 dated 06/04/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ACURATE TABLETS ((Paracetamol 450mg + Doxylamine Succinate 5mg + Caffeine 30mg + Codeine Phosphate 10mg + Color Quinoline Yellow 2Mg) (Para - 22500.000+Doxy- 250.000+Caffeine-1500.000 + Codeine-500.000 + Colour- 100.000Kgs) Total KGS- 24850.000 (No. of Tablets - 50000000))	50000000 Numbers	1	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	255.0 kg.
		2	CAFFEINE BP/Ph. Eur	1530.0 kg.
		3	CODEINE PHOSPHATE BP/USP/EP/PH.EUR	510.0 kg.

50000000))		4	COLOUR QUINOLINE YELLOW CI 47005 (SPECTRACOL)	100.0 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	127 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	CITO CHEM INDUSTRIES PVT.LTD.
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005923AM24
RA File Number	56AX04000305 AM24
Licence No and Date	5611002219/27/09/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Jul/202122/4 dated 15/07/2021** against advance authorization **No. 0311001323 dated 28/01/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Clobatasol Propionate	1000 kg.	1	Betamethasone	1000 kg.

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

Case No.	128 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00005996AM24
RA File Number	03AX04003005 AM24
Licence No and Date	0311027533/03/10/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Jul/202122/4 dated 15/07/2021** against advance authorization **No. 0311004820 dated 22/06/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Doxycycline Hyclate DR Tablets USP 100 mg , 100 S US((9,900 Bottles X 100 Per Bottles = 9,90,000 Tablets) (Total Weight of Export Product = 99.000 Kgs) (Net Content weight of Import Product = 120.582 kgs))	990000 Tablets	1	Doxycycline Hyclate USP	114.247 kg.

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

Case No.	129 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006000AM24
RA File Number	08AX04001244 AM24
Licence No and Date	0811009510/03/10/2023

Norms Committee Decision:

The committee considered the request of firm for fixation of ad-hoc norms and it has been observed that the strength of the second export item not mentioned in the application, it was decided that firm was asked to clarify the second export item in line with DML.

Case No.	130 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006002AM24
RA File Number	08AX04001243 AM24
Licence No and Date	0811009509/03/10/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Oct/202324/15 dated 13/10/2023** against advance authorization **No. 0811003993 dated 08/02/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Phenylephrine Hydrochloride Injection USP, 10 mg/mL (10 mL) (Phenylephrine Hydrochloride Injection USP, 10 mg/mL (10 mL))	1 Number	1	PHENYLEPHRINE HCL USP	110.00 mg

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

Case No.	131 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006019AM24
RA File Number	34AX04000513 AM24
Licence No and Date	3411004189/03/10/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No. 3411003649 dated 29/04/2023**, 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. allowed.
Tretinoin Cream USP 0.1% - 20gm Tube (Tretinoin Cream USP 0.1% - 20gm Tube (net content of active ingredients 800.00 gm))	40000 Number	1	Tretinoin USP	816 gm.

Tretinoin Cream USP 0.1% - 45 gm Tube (Tretinoin Cream USP 0.1% - 45 gm Tube (net content of active ingredients 2250.00 gm))	50000 Number	2	Tretinoin USP	2295 gm.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	132 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006030AM24
RA File Number	03AX04002969 AM24
Licence No and Date	0311027604/04/10/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Jan/202324/21 dated 24/01/2024** against advance authorization **No. 0311030155 dated 13/01/2024**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Bempedoic Acid & Ezetimibe Fixed Dose Combination Tablets (Each Tablet content Bempedoic Acid 180 mg & Ezetimibe 10 mg ((Net content of Bempedoic Acid 162.000 kgs & Ezetimibe 9.000 kgs in total Export Qty) (AA for Free of cost material as per Para 4.11 of HBP & Para 4.19 of FTP & RBI Master Circular C-26 - Disallowing remittances for material being supplied free cost))	1 Number	1	Bempedoic Acid	189.90 mg.
		2	Ezetimibe	10.55 mg.

Note: The above norms are valid only for subject to fulfilment 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.	133 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	REMEDIUM LIFECARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006031AM24
RA File Number	03AX04002475 AM24
Licence No and Date	0311027606/04/10/2023
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 along with relevant documents from the firm.	

Case No.	134 / NC/3/MEET/Feb/202324/23										
Case Status	Case Approved										
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024										
HQ File Number	HQRNORM APPLY 00006047AM24										
RA File Number	08AX04001273 AM24										
Licence No and Date	0811009529/05/10/2023										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting No. NC/3/MEET/Oct/202324/15 dated 13/10/2023 against advance authorization No. 0811003993 dated 08/02/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Phenylephrine Hydrochloride Injection USP, 10 mg/mL (1 mL)</td><td>1 Number</td><td>1</td><td>PHENYLEPHRINE HCL USP</td><td>11.00 mg</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Phenylephrine Hydrochloride Injection USP, 10 mg/mL (1 mL)	1 Number	1	PHENYLEPHRINE HCL USP	11.00 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Phenylephrine Hydrochloride Injection USP, 10 mg/mL (1 mL)	1 Number	1	PHENYLEPHRINE HCL USP	11.00 mg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	135 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006054AM24
RA File Number	31AX04000170 AM24
Licence No and Date	3111002689/05/10/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Mar/202223/24 dated 13/04/2023** against advance authorization **No. 0311001608 dated 03/08/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TYLODOX - GOLD WSP (Pack size 1 Kgs Jar)(Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)	1 Number	1	Tylosin Tartrate BP/USP /EP	0.101 kg.
		2	Doxycycline Hyclate BP/EP/USP	0.202 kg.
TYLODOX - GOLD WSP (Pack size 100 Gms sachet)(Each gram contains: Tylosin Tartrate BP (Vet) 100 mg, Doxycycline Hyclate BP 200 mg)	1 Number	3	Tylosin Tartrate BP/USP /EP	10.1 gm
		4	Doxycycline Hyclate BP/EP/USP	20.2 gm
GENTADOX GOLD 100 / 200 (pack Size 1 Kgs Jar)(Each gram powder contains: Doxycycline Hyclate BP 200mg, Gentamycin Sulphate USP 100mg)	1 Number	5	Doxycycline Hyclate BP/EP/USP	0.202 kg.
GENTADOX GOLD 100 /200 (pack Size 100 Gms Sachet)(Each gram powder contains: Doxycycline Hyclate BP 200mg, Gentamycin Sulphate USP 100mg)	1 Number	6	Doxycycline Hyclate BP/EP/USP	20.2 gm
NEODOX - GOLD WSP (pack Size 1 Kgs Jar)(Each gram contains: Doxycycline Hyclate	1 Number	7	Doxycycline Hyclate BP/EP/USP	0.101 kg.

BP 100 mg Neomycin Sulfate BP 100 mg)				
NEODOX - GOLD WSP (pack Size 100 Gms Sachet) (Each gram contains: Doxycycline Hyclate BP 100 mg Neomycin Sulfate BP 100 mg)	1 Number	8	Doxycycline Hyclate BP/EP/USP	10.1 gm
RA concerned may take further necessary action as per above decision of NC.				

Case No.	136 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	PANACEA BIOTEC PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006096AM24
RA File Number	05AX04002038 AM24
Licence No and Date	0511021399/09/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	137 / NC/3/MEET/Feb/202324/23					
Case Status	Case Approved					
Party Name	TORRENT PHARMACEUTICALS LTD					
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024					
HQ File Number	HQRNORM APPLY 00006109AM24					
RA File Number	08AX04001276 AM24					
Licence No and Date	0811009604/09/10/2023					
Norms Committee Decision:						
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting No. NC/3/MEET/Jun/202324/8 dated 30/06/2023 against advance authorization No. 0811007571 dated 15/03/2023 , 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:-						
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty. allowed.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.		

BISOPROLOL FUMARATE TABLETS 1.25 MG (EACH FILM COATED TABLET CONTAINS: BISOPROLOL FUMARATE USP 1.25 MG NET CONTENT OF BISOPROLOL FUMARATE SHOULD NOT BE LESS THAN 1.125 KG IN EXPORT ITEM.)	1 Number	1	BISOPROLOL FUMARATE USP	1.275 mg/1.25 mg tablet
BISOPROLOL FUMARATE TABLETS 2.5 MG (EACH FILM COATED TABLET CONTAINS: BISOPROLOL FUMARATE USP 2.5 MG NET CONTENT OF BISOPROLOL FUMARATE SHOULD NOT BE LESS THAN 3.00 KG IN EXPORT ITEM.)	1 Number	2	BISOPROLOL FUMARATE USP	2.55 mg/2.5 mg tablet
BISOPROLOL FUMARATE TABLETS 5 MG (EACH FILM COATED TABLET CONTAINS: BISOPROLOL FUMARATE USP 5 MG NET CONTENT OF BISOPROLOL FUMARATE SHOULD NOT BE LESS THAN 13.500 KG IN EXPORT ITEM.)	1 Number	3	BISOPROLOL FUMARATE USP	5.10 mg/5 mg tablet
BISOPROLOL FUMARATE TABLETS 10 MG (EACH FILM COATED TABLET CONTAINS: BISOPROLOL FUMARATE USP 10 MG NET CONTENT OF BISOPROLOL FUMARATE SHOULD NOT BE LESS THAN 30.000 KG IN EXPORT ITEM.)	1 Number	4	BISOPROLOL FUMARATE USP	10.20 mg/10 mg tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	138 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006119AM24
RA File Number	03AX04003131 AM24

Licence No and Date	0311027738/09/10/2023																			
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/Sep/202324/14 dated 27/09/2023 against advance authorization No.0311026446 dated 18/08/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																				
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="3">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></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	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. allowed.																
OCTYLATED DIPHENYLAMINE (OCD FLAKES/POWDER)	1 kg.	1	DIPHENYLAMINE	0.50 kg.																
		2	DI ISOBUTYLENE	0.64 kg.																
		3	ACTIVATED CLAY	0.10 kg.																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	139 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	CHEMIKER PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006178AM24
RA File Number	50AX04000062 AM24
Licence No and Date	5011001072/11/10/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	140 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006182AM24
RA File Number	08AX04001270 AM24
Licence No and Date	0811009637/11/10/2023

Norms Committee Decision:

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

Case No.	141 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006184AM24
RA File Number	52AX04001763 AM23
Licence No and Date	5211005979/12/10/2023

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. allowed.
1-(2-(2-HYDROXYETHOXY)ETHYL) PIPERAZINE	1 kg.	1	PIPERAZINE ANHYDROUS	1.00 kg.

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

Case No.	142 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006189AM24
RA File Number	09AX04000621 AM24
Licence No and Date	0911005970/12/10/2023

Norms Committee Decision:

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

Case No.	143 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024

and Date	
HQ File Number	HQRNORM APPLY 00006200AM24
RA File Number	08AX04001277 AM24
Licence No and Date	0811009642/12/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	144 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006202AM24
RA File Number	03AX04003026 AM24
Licence No and Date	0311027846/12/10/2023

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/Sep/202324/14 dated 27/09/2023** against advance authorization **No.0311026848 dated 04/09/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
GLIPIZIDE EXTENDED RELEASE TABLETS 10 MG.(Each tablet contains (i) Eastman (TM Cellulose Acetate (CA 398- 10NF/EP)- 29.70 mg (ii) Sentry Polyox WSR N80 FP NF- 178.10 mg (iii) Sentry Polyox WSR 303 NF- 100 mg. Net content (i) 820.16 Kgs (ii) 4918.18 Kgs (iii) 2761.47 Kgs.)	1 Number	1	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	29.70 mg.
		2	SENTRY POLYOX WSR N80 FP NF	178.10 mg
		3	SENTRY POLYOX WSR 303 NF	100.00 mg
GLIPIZIDE EXTENDED RELEASE TABLETS 5 MG.(Each tablet contains (i) Eastman (TM Cellulose Acetate (CA 398- 10NF/EP)- 20.40 mg (ii) Sentry Polyox WSR N80 FP NF- 89.05 mg (iii) Sentry Polyox WSR 303 NF- 50 mg. Net content (i) 430.05 Kgs (ii) 1877.27	1 Number	4	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	20.40 mg
		5	SENTRY POLYOX WSR N80 FP NF	89.05 mg

Kgs (iii) 1054.06 Kgs.)		6	SENTRY POLYOX WSR 303 NF	50.00 mg
GLIPIZIDE EXTENDED RELEASE TABLETS 2.5 MG.(Each tablet contains (i) Eastman (TM Cellulose Acetate (CA 398- 10NF/EP)- 20.40 mg (ii) Sentry Polyox WSR N80 FP NF- 89.05 mg (iii) Sentry Polyox WSR 303 NF- 50 mg. Net content (i) 231.08 Kgs (ii) 1008.71 Kgs (iii) 566.37 Kgs.)	1 Number	7	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	20.40 mg
		8	SENTRY POLYOX WSR N80 FP NF	89.05 mg
		9	SENTRY POLYOX WSR 303 NF	50.00 mg

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

Case No.	145 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006208AM24
RA File Number	34AX04000546 AM24
Licence No and Date	3411004225/12/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	146 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006250AM24
RA File Number	08AX04001324 AM24
Licence No and Date	0811009657/13/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	147 / NC/3/MEET/Feb/202324/23
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Case Status	Case Approved																
Party Name	ETERNIS FINE CHEMICALS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024																
HQ File Number	HQRNORM APPLY 00006262AM24																
RA File Number	03AX04003185 AM24																
Licence No and Date	0311027906/16/10/2023																
Norms Committee Decision:																	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																	
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">Coeur Amber Eternis (Ambercore)</td><td rowspan="2">1 kg.</td><td>1</td><td>ORTHO TERTIARY BUTYL PHENOL</td><td>0.79 kg.</td></tr><tr><td>2</td><td>1,2 Epoxy butane</td><td>0.379 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Coeur Amber Eternis (Ambercore)	1 kg.	1	ORTHO TERTIARY BUTYL PHENOL	0.79 kg.	2	1,2 Epoxy butane	0.379 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.													
Coeur Amber Eternis (Ambercore)	1 kg.	1	ORTHO TERTIARY BUTYL PHENOL	0.79 kg.													
		2	1,2 Epoxy butane	0.379 kg.													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	148 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	PRIVI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006295AM24
RA File Number	03AX04003186 AM24
Licence No and Date	0311027939/17/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	149 / NC/3/MEET/Feb/202324/23			
Case Status	Case Approved			
Party Name	FDC LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024			
HQ File Number	HQRNORM APPLY 00006301AM24			
RA File Number	03AX04003276 AM24			

Licence No and Date	0311027949/17/10/2023																		
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/202324/20 dated 18/01/2024 against advance authorization No.0511018497 dated 25/04/2023 , 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><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>OFLOXACIN OPHTHALMIC SOL 0.3% 5.0ML (OFLOXACIN EYE DROPS 5 ML)((EACH VIAL CONTAINS OFLOXACIN 0.015 GM NET WT OF BULK DRUG IS 28.080 KGS))</td><td>1 Number</td><td>1</td><td>OFLOXACIN</td><td>15.30 mg</td></tr><tr><td>OFLOXACIN OPHTHALMIC SOL 0.3% 10.0ML (OFLOXACIN EYE DROPS 10 ML)((EACH VIAL CONTAINS OFLOXACIN 0.03 GM NET WT OF BULK DRUG IS 7.440 KGS))</td><td>1 Number</td><td>2</td><td>OFLOXACIN</td><td>30.60 mg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	OFLOXACIN OPHTHALMIC SOL 0.3% 5.0ML (OFLOXACIN EYE DROPS 5 ML)((EACH VIAL CONTAINS OFLOXACIN 0.015 GM NET WT OF BULK DRUG IS 28.080 KGS))	1 Number	1	OFLOXACIN	15.30 mg	OFLOXACIN OPHTHALMIC SOL 0.3% 10.0ML (OFLOXACIN EYE DROPS 10 ML)((EACH VIAL CONTAINS OFLOXACIN 0.03 GM NET WT OF BULK DRUG IS 7.440 KGS))	1 Number	2	OFLOXACIN	30.60 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
OFLOXACIN OPHTHALMIC SOL 0.3% 5.0ML (OFLOXACIN EYE DROPS 5 ML)((EACH VIAL CONTAINS OFLOXACIN 0.015 GM NET WT OF BULK DRUG IS 28.080 KGS))	1 Number	1	OFLOXACIN	15.30 mg															
OFLOXACIN OPHTHALMIC SOL 0.3% 10.0ML (OFLOXACIN EYE DROPS 10 ML)((EACH VIAL CONTAINS OFLOXACIN 0.03 GM NET WT OF BULK DRUG IS 7.440 KGS))	1 Number	2	OFLOXACIN	30.60 mg															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	150 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	PRASHI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006329AM24
RA File Number	03AX04003293 AM24
Licence No and Date	0311028015/18/10/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	151 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006330AM24

RA File Number	08AX04001178 AM24																		
Licence No and Date	0811009695/18/10/2023																		
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/Dec/202324/17 dated 20/12/2023 against advance authorization No.0810146231 dated 25/09/2019, 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 border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop 5 mL.</td> <td>90,000 Numbers</td> <td>1</td> <td>Metamizole Magnesium</td> <td>143.654 kg.</td> </tr> <tr> <td>Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop 15 mL.</td> <td>13,00,000 Numbers</td> <td></td> <td>Metamizole Magnesium</td> <td>6142.50 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop 5 mL.	90,000 Numbers	1	Metamizole Magnesium	143.654 kg.	Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop 15 mL.	13,00,000 Numbers		Metamizole Magnesium	6142.50 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop 5 mL.	90,000 Numbers	1	Metamizole Magnesium	143.654 kg.															
Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop 15 mL.	13,00,000 Numbers		Metamizole Magnesium	6142.50 kg.															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	152 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006333AM24
RA File Number	08AX04001249 AM24
Licence No and Date	0811009697/18/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	153 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006334AM24
RA File Number	08AX04001262 AM24

Licence No and Date	0811009700/18/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	154 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006335AM24
RA File Number	05AX04002187 AM24
Licence No and Date	0511021614/18/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	155 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006356AM24
RA File Number	30AX04000323 AM24
Licence No and Date	3011004322/19/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	156 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006363AM24
RA File Number	03AX04003340 AM24
Licence No and Date	0311028059/19/10/2023
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/Sep/202324/14 dated 27/09/2023 against advance authorization No.0311026446 dated 18/08/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
OCTYLATED DIPHENYLAMINE (OCD FLAKES/POWDER)	1 kg.	1	DIPHENYLAMINE	0.50 kg.
		2	DI ISOBUTYLENE	0.64 kg.
		3	ACTIVATED CLAY	0.10 kg.

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

Case No.	157 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	INTIGREAT CONSULTING SERVICES LLP
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006403AM24
RA File Number	03AX04003028 AM24
Licence No and Date	0311028103/23/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	158 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	SANDOZ PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006418AM24
RA File Number	03AX04003201 AM24
Licence No and Date	0311028115/23/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	159 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred

Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006420AM24
RA File Number	03AX04003262 AM24
Licence No and Date	0311028121/23/10/2023
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 along with relevant documents from the firm:	

Case No.	160 / NC/3/MEET/Feb/202324/23													
Case Status	Case Approved													
Party Name	FREESIA CHEMICALS													
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024													
HQ File Number	HQRNORM APPLY 00006426AM24													
RA File Number	03AX04002817 AM24													
Licence No and Date	0311028138/25/10/2023													
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/Sep/202324/14 dated 27/09/2023 against advance authorization No. 0311016342 dated 14/07/2022 , 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:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Cyclopentanone (CAS No. 120-92-3)</td><td>1 kg.</td><td>1</td><td>Adipic Acid</td><td>1.93 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Cyclopentanone (CAS No. 120-92-3)	1 kg.	1	Adipic Acid	1.93 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Cyclopentanone (CAS No. 120-92-3)	1 kg.	1	Adipic Acid	1.93 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	161 / NC/3/MEET/Feb/202324/23			
Case Status	Case Approved			
Party Name	NEXUS PHARMA CHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024			
HQ File Number	HQRNORM APPLY 00006434AM24			
RA File Number	08AX04001338 AM24			
Licence No and	0811009742/25/10/2023			

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. 10/82-ALC4/2018 dated 16/10/2018 against advance authorization No.0810136408 dated 02.11.2015, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Prednisolone Sodium Phosphate BP</td> <td>1 kg.</td> <td>1</td> <td>Prednisolone IP</td> <td>0.839 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Prednisolone Sodium Phosphate BP	1 kg.	1	Prednisolone IP	0.839 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Prednisolone Sodium Phosphate BP	1 kg.	1	Prednisolone IP	0.839 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	162 / NC/3/MEET/Feb/202324/23													
Case Status	Case Approved													
Party Name	AURORE LIFE SCIENCES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024													
HQ File Number	HQRNORM APPLY 00006452AM24													
RA File Number	09AX04000686 AM24													
Licence No and Date	0911006081/26/10/2023													
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/202324/20 dated 18/01/2024 against advance authorization No.0911004999 dated 09/05/2023, 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:-														
<table border="1"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Valganciclovir HCl</td> <td>1 kg.</td> <td>1</td> <td>Ganciclovir</td> <td>1.75 kg.</td> </tr> </tbody> </table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Valganciclovir HCl	1 kg.	1	Ganciclovir	1.75 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Valganciclovir HCl	1 kg.	1	Ganciclovir	1.75 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	163 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006454AM24
RA File Number	03AX04003224 AM24
Licence No and Date	0311028189/26/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	164 / NC/3/MEET/Feb/202324/23										
Case Status	Case Approved										
Party Name	MICRO LABS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024										
HQ File Number	HQRNORM APPLY 00006457AM24										
RA File Number	07AX04001166 AM24										
Licence No and Date	0711009545/26/10/2023										
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.0711005078 dated 23/08/2022 , 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. allowed.</th></tr><tr><td>PREMIX OF NIFUROXAZIDE (1GM OF PREMIX CONTAINS 0.552 GMS OF NIFUROXAZIDE) NET CONTENT 2980.80KGS)</td><td>5400 kg.</td><td>1</td><td>NIFUROXAZIDE BP/EP</td><td>3010.61 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	PREMIX OF NIFUROXAZIDE (1GM OF PREMIX CONTAINS 0.552 GMS OF NIFUROXAZIDE) NET CONTENT 2980.80KGS)	5400 kg.	1	NIFUROXAZIDE BP/EP	3010.61 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
PREMIX OF NIFUROXAZIDE (1GM OF PREMIX CONTAINS 0.552 GMS OF NIFUROXAZIDE) NET CONTENT 2980.80KGS)	5400 kg.	1	NIFUROXAZIDE BP/EP	3010.61 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	165 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	MICRO LABS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024														
HQ File Number	HQRNORM APPLY 00006458AM24														
RA File Number	07AX04001167 AM24														
Licence No and Date	0711009546/26/10/2023														
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.0711004100 dated 26/05/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-															
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>DICLOXACILLIN CAPSULES 500MG (1500.00KG))</td><td>3,000,000 Numbers</td><td>1</td><td>DICLOXACILLIN SODIUM E.P.</td><td>1605 kg.</td></tr></table>						Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DICLOXACILLIN CAPSULES 500MG (1500.00KG))	3,000,000 Numbers	1	DICLOXACILLIN SODIUM E.P.	1605 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.											
DICLOXACILLIN CAPSULES 500MG (1500.00KG))	3,000,000 Numbers	1	DICLOXACILLIN SODIUM E.P.	1605 kg.											
RA concerned may take further necessary action as per above decision of NC.															

Case No.	166 / NC/3/MEET/Feb/202324/23			
Case Status	Case Approved			
Party Name	YASHO INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024			
HQ File Number	HQRNORM APPLY 00006462AM24			
RA File Number	03AX04003436 AM24			
Licence No and Date	0311028216/26/10/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

thiadizole (YALUB DM -113))		3	TERT -NONYL MERCAPTAN (S-MERCAPTAN)	0.700 kg.
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RA concerned may take further necessary action as per above decision of NC.

Case No.	167 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006470AM24
RA File Number	07AX04001168 AM24
Licence No and Date	0711009558/27/10/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	168 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006479AM24
RA File Number	03AX04003049 AM24
Licence No and Date	0311028247/27/10/2023
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 along with relevant documents from the firm:	

Case No.	169 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006481AM24
RA File Number	03AX04003424 AM24
Licence No and Date	0311028257/27/10/2023
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DOXYLEB CAPSULE (DOXYCYCLINE HYCLATE CAPSULE BP) 100MG (IN PACKING OF 10x10s, 10x100s & 1000s. QTY CONSUMED OF EXEMPT MATERIAL DOXYCYCLINE HYCLATE BP-115.400MG/CAPSULE)	1 Number	1	DOXYCYCLINE HYCLATE BP	115.40 mg / capsule

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

Case No.	170 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006486AM24
RA File Number	03AX04003432 AM24
Licence No and Date	0311028267/27/10/2023

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/202324/21 dated 24/01/2024** against advance authorization **No.0311023542 dated 12/05/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CHLORAMPHENICOL EYE DROPS 10 ML (CLOROGEN , CLORAH AND VANMYCETIN EYE DROPS 10 ML) (EACH VIAL CONTAINS CHLORAMPHENICOL MICRONIZED 0.050GM)	1 Number	1	CHLORAMPHENICOL MICRONIZED	51.00 mg/vial

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

Case No.	171 / NC/3/MEET/Feb/202324/23
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006503AM24
RA File Number	03AX04003414 AM24
Licence No and Date	0311028288/30/10/2023

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/202324/21 dated 24/01/2024** against advance authorization **No.0311029131 dated 05/12/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
HEXAFLUOROISOPROPYL METHYLETHER(HFMOP)	1 kg.	1	HEXA FLUOROISOPROPANOL	0.970 kg.

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

Case No.	172 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	METROCHEM API PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006520AM24
RA File Number	09AX04000671 AM24
Licence No and Date	0911006113/30/10/2023

Norms Committee Decision:

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

Case No.	173 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006537AM24
RA File Number	05AX04002270 AM24

Licence No and Date	0511021818/31/10/2023
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to refer the case to Department of Bio-Technology for obtaining their comments.	

Case No.	174 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	VIRCHOW PETROCHEMICAL PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006566AM24
RA File Number	09AX04000607 AM24
Licence No and Date	0911006121/31/10/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	175 / NC/3/MEET/Feb/202324/23
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Feb/ 202324/ 23 and 19/02/2024
HQ File Number	HQRNORM APPLY 00006567AM24
RA File Number	08AX04001381 AM24
Licence No and Date	0811009826/31/10/2023
Norms Committee Decision: The case is under consideration for want of comments of TE.	