



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

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

(DES - III SECTION)**MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Jan/202223/18**DATED:** 23/01/2023Please Note

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

Meeting No. NC/3/MEET/Jan/202223/18 dated 23/01/2023 of Norms Committee - III for the year 2022-23 was held on 23/01/2023 under the Chairmanship of Rajiv Soni ,Joint DGFT to consider the following applications for ratification of norms in respect of advance authorizations under Duty Exemption Scheme (Chapter-4) of Foreign Trade Policy 2015-20.

The following members were present in the meeting:-

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

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Jan/202223/18													
Case Status	Case Approved													
Party Name	S.M. HERBALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM REVIW00004282AM23													
RA File Number	052404000147 AM13													
Licence No and Date	0510330512/25/07/2012													
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was decided to revise adhoc 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.</th> </tr> </thead> <tbody> <tr> <td>Camptothecin (CHEMICAL) HPLC Purity NLT 98.5% (Average purity as per COA, NLT 99%)</td> <td>1 kg</td> <td>1</td> <td>Crude Camptothecin (CHEMICAL) HPLC Purity NLT 90% (Average purity as per COA, NMT 91.1%)</td> <td>1.10 kg</td> </tr> </tbody> </table>					Export product	Qty.	Sl. No.	Import items	Qty.	Camptothecin (CHEMICAL) HPLC Purity NLT 98.5% (Average purity as per COA, NLT 99%)	1 kg	1	Crude Camptothecin (CHEMICAL) HPLC Purity NLT 90% (Average purity as per COA, NMT 91.1%)	1.10 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Camptothecin (CHEMICAL) HPLC Purity NLT 98.5% (Average purity as per COA, NLT 99%)	1 kg	1	Crude Camptothecin (CHEMICAL) HPLC Purity NLT 90% (Average purity as per COA, NMT 91.1%)	1.10 kg										
Note: Above revised norms are for regularization and closure purpose only.														
RA concerned may take further necessary action as per above decision of NC.														

Case No.	2 / NC/3/MEET/Jan/202223/18			
Case Status	Case Rejected			
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM REVIW00001497AM23			
RA File Number	039504000262 AM13			
Licence No and Date	0310705888/22/08/2012			
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case.				

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

Case No.	3 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	S.M. HERBALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004283AM23
RA File Number	052404000239 AM14
Licence No and Date	0510367886/08/10/2013

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Quinoline Based Alkoliod - Camptothecin (Chemical) HPLC Purity NLT 98.5% (Average purity as per COA, NLT 99%)	1 kg	1	Quinoline Based Alkaloid-Camptothecin (Chemical) HPLC Purity NLT 90% (Average purity as per COA, NMT 90.55%)	1.085 kg
Note: Above revised norms are for regularization and closure purpose only.				

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

Case No.	4 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	S.M. HERBALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004285AM23
RA File Number	052404000321 AM14
Licence No and Date	0510374573/27/12/2013

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
10 Deacetyl Baccatin III HPLC Purity NLT 98.5% (Average purity as per COA, NLT 99.4%)	1 kg	1	Ketones in Carbonyl Group 10 Deacetyl Baccatin - III HPLC Purity NLT 95% (Average purity as per COA, NMT 95.11%)	1.05 kg
Note: Above revised norms are for regularization and closure purpose only.				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	5 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	VENKATA NARAYANA ACTIVE INGREDIENTS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM REVIW00004193AM23			
RA File Number	042404000248 AM15			
Licence No and Date	0410159986/07/01/2015			
Norms Committee Decision:				
The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Sitagliptin Phosphate (APIs / Bulk Drugs)	1 kg	1	2,4,5 – Trifluorophenylacetic Acid	1.167 kg
		2	Meldrum Acid	0.77 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	6 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred

Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004183AM23
RA File Number	522404000058 AM15
Licence No and Date	5210041428/13/02/2015
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information / documents from the firm: i. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. ii. Stepwise justification for wastage.	

Case No.	7 / NC/3/MEET/Jan/202223/18																
Case Status	Case Approved																
Party Name	VENKATA NARAYANA ACTIVE INGREDIENTS PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023																
HQ File Number	HQRNORM REVIW00004194AM23																
RA File Number	042404000003 AM16																
Licence No and Date	0410160438/24/04/2015																
Norms Committee Decision:																	
The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:																	
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="2">Sitagliptin Phosphate (APIs / Bulk Drugs)</td><td rowspan="2">1 kg</td><td>1</td><td>2,4,5 – Trifluorophenylacetic Acid</td><td>1.167 kg</td></tr><tr><td>2</td><td>Meldrum Acid</td><td>0.77 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	Sitagliptin Phosphate (APIs / Bulk Drugs)	1 kg	1	2,4,5 – Trifluorophenylacetic Acid	1.167 kg	2	Meldrum Acid	0.77 kg
Export product	Qty.	Sl. No.	Import items	Qty.													
Sitagliptin Phosphate (APIs / Bulk Drugs)	1 kg	1	2,4,5 – Trifluorophenylacetic Acid	1.167 kg													
		2	Meldrum Acid	0.77 kg													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	8 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004182AM23
RA File Number	522404000034 AM16
Licence No and Date	5210041610/14/08/2015
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information / documents from the firm: i. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. ii. Stepwise justification for wastage.	

Case No.	9 / NC/3/MEET/Jan/202223/18																
Case Status	Case Approved																
Party Name	PAYAL POLYPLAST PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023																
HQ File Number	HQRNORM REVIW00004098AM23																
RA File Number	052404000418 AM16																
Licence No and Date	0510396612/14/12/2015																
Norms Committee Decision:																	
The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No. 0510408806 dated 06/12/2018 , it was decided to revise adhoc norms as under:																	
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="2">Di-Octyl Tere Phthalate (DOTP)</td><td rowspan="2">1 kg</td><td>1</td><td>Pure Terephthalic Acid</td><td>0.447 kg</td></tr><tr><td>2</td><td>2 Ethyl Hexanol</td><td>0.680 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	Di-Octyl Tere Phthalate (DOTP)	1 kg	1	Pure Terephthalic Acid	0.447 kg	2	2 Ethyl Hexanol	0.680 kg
Export product	Qty.	Sl. No.	Import items	Qty.													
Di-Octyl Tere Phthalate (DOTP)	1 kg	1	Pure Terephthalic Acid	0.447 kg													
		2	2 Ethyl Hexanol	0.680 kg													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	10 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004145AM23
RA File Number	039404001096 AM16
Licence No and Date	0310803709/01/04/2016

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No **NC/3/MEET/May/202223/3 dated 27/05/2022** against advance authorization No. **0310801629 dated 07.01.2016, 0310801603 dated 06.01.2016, 0310801571 dated 05.01.2016 and 0310801604 dated 06.01.2016**, it was decided to revise adhoc norms as under:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. (in gm for 100 lozenges)
1	Diffiam Sugar Free Lozenges Flavours Raspberry/Eucalyptus & Menthol/Honey & Lemon/ Orange/ Double Mint.(Each lozenge contains Benzydamine Hydrchloride 3.00 mg, Cetylpyridinium Chloride 1.33 mg, Isomalt ST-M 2591.86 mg. Net Content Benzydamine Hydrchloride 73.001 Kgs, Cetylpyridinium Chloride 32.364 Kgs, Isomalt ST-M 63069.284 Kgs.)	100 lozenges	1	Benzydamine Hydrochloride	0.306 gram
			2	Cetylpyridinium Chloride	0.1356 gram
			3	Isomalt ST-M	259.186 gram
2	Diffiam AAA Sugar Free Lozenges Flavours Eucalyptus & Menthol/Honey & Lemon/Black Currant/Berry.(Each lozenge contains Benzydamine Hydrchloride 3.00 mg, Isomalt ST-M 2591.86 mg. Net Content Benzydamine Hydrchloride 98.546 Kgs, Isomalt ST-M 85139.491 Kgs)	100 lozenges	4	Benzydamine Hydrochloride	0.306 gram
			5	Isomalt ST-M	259.186 gram
3	Diffiam Sugar Free Lozenges Mint Fresh Flavour.(Each lozenge contains Benzydamine Hydrchloride 3.00 mg, Isomalt ST-M 2591.86 mg. Net Content Benzydamine Hydrchloride 47.446 Kgs, Isomalt ST-M 40991.365 Kgs)	100 lozenges	6	Benzydamine Hydrochloride	0.306 gram
			7	Isomalt ST-M	259.186 gram
4	Septolete Lozenges/ Septolete Extra Lozenges /Septolete Ultra Lozenges / Septolete Omni Lozenges /(Septolete Total Lozenges / Septolete Duo Lozenges/ Septabene Lozenges. Each lozenge contains Cetylpyridinium Chloride EP 1.00 MG,,	100 lozenges	8	Cetylpyridinium Chloride	0.102 gram
			9	Isomalt ST-M	259.186 gram

	Isomalt ST-M 2591.86 MG. Net Content Cetylpyridinium Chloride 40.876 Kgs, Isomalt ST-M 105944.70 Kgs.)				
RA concerned may take further necessary action as per above decision of NC.					

Case No.	11 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004184AM23
RA File Number	522404000042 AM17
Licence No and Date	5210042032/30/09/2016
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information / documents from the firm:	
i. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. ii. Stepwise justification for wastage.	

Case No.	12 / NC/3/MEET/Jan/202223/18				
Case Status	Case Approved				
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023				
HQ File Number	HQRNORM REVIW00004110AM23				
RA File Number	318304000187 AM17				
Licence No and Date	3110066649/31/03/2017				
Norms Committee Decision:					
The Committee considered the request of firm for review of adhoc norms and it was decided to revise adhoc norms as under:					
Export product		Qty.	Sl. No.	Import items	Qty.

2,3,6-Trimethyl Phenol (TMP)	1 kg	1	Meta Cresol (MC99)	0.982 kg
		2	Methanol	0.575 kg
		3	Catalyst (Katalco 71-5)	0.027 kg

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

Case No.	13 / NC/3/MEET/Jan/202223/18																
Case Status	Case Approved																
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023																
HQ File Number	HQRNORM REVIW00004113AM23																
RA File Number	318304000010 AM18																
Licence No and Date	3110066712/01/05/2017																
Norms Committee Decision:																	
The Committee considered the request of firm for review of adhoc norms and it was decided to revise adhoc norms as under:																	
<table><tr><th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr><tr><td rowspan="2">2,6 Xylidine</td><td rowspan="2">500 MT</td><td>1</td><td>2,6 xylenol</td><td>700.00 MT</td></tr><tr><td>2</td><td>Catalyst [PD on Alumina Catalyst (Pd content 0.4% -0.5%)]</td><td>0.805 MT</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	2,6 Xylidine	500 MT	1	2,6 xylenol	700.00 MT	2	Catalyst [PD on Alumina Catalyst (Pd content 0.4% -0.5%)]	0.805 MT
Export product	Qty.	Sl. No.	Import items	Qty.													
2,6 Xylidine	500 MT	1	2,6 xylenol	700.00 MT													
		2	Catalyst [PD on Alumina Catalyst (Pd content 0.4% -0.5%)]	0.805 MT													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	14 / NC/3/MEET/Jan/202223/18			
Case Status	Case Rejected			
Party Name	SHREE GANESH REMEDIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM REVIW00002092AM23			
RA File Number	342404000340 AM18			

Licence No and Date	3410043947/09/03/2018
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	15 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SHREE GANESH REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00002113AM23
RA File Number	342404000399 AM19
Licence No and Date	3410045006/28/03/2019
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	16 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SYMBIOSIS PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00000804AM23
RA File Number	332404000002 AM20
Licence No and Date	3310030527/16/04/2019
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: i. DML / Approved Composition of export product. ii. Detail of Gelatin is confusing. Please clarify it.	

Case No.	17 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	018205001022AM20
RA File Number	052404000669 AM20
Licence No and Date	0510413373/17/01/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	18 / NC/3/MEET/Jan/202223/18																			
Case Status	Case Approved																			
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD																			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023																			
HQ File Number	HQRNORM REVIW00004128AM23																			
RA File Number	039504000985 AM20																			
Licence No and Date	0310834682/06/02/2020																			
Norms Committee Decision:																				
The Committee considered the request of firm for fixation of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No NC/3/MEET/Sep/202223/8 dated 23/09/2022 against advance authorization No. 0311008242 dated 03/11/2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:																				
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="3">2 ETHYLHEXYL DIPHENYL PHSOPHITE (2 EHDP)</td><td rowspan="3">1 kg</td><td>1</td><td>PHENOL</td><td>0.604 kg</td></tr><tr><td>2</td><td>ETHYLHEXANOL</td><td>0.386 kg</td></tr><tr><td>3</td><td>YELLOW PHOSPHORUS</td><td>0.0966 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	2 ETHYLHEXYL DIPHENYL PHSOPHITE (2 EHDP)	1 kg	1	PHENOL	0.604 kg	2	ETHYLHEXANOL	0.386 kg	3	YELLOW PHOSPHORUS	0.0966 kg
Export product	Qty.	Sl. No.	Import items	Qty.																
2 ETHYLHEXYL DIPHENYL PHSOPHITE (2 EHDP)	1 kg	1	PHENOL	0.604 kg																
		2	ETHYLHEXANOL	0.386 kg																
		3	YELLOW PHOSPHORUS	0.0966 kg																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	19 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved

Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM REVIW00004129AM23			
RA File Number	039504001128 AM20			
Licence No and Date	0310835301/09/03/2020			
Norms Committee Decision:				
The Committee considered the request of firm for fixation of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No NC/3/MEET/Dec/202223/15 dated 29/12/2022 against advance authorization No. 0311015330 dated 08/06/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
TRIPHENYL PHOSPHITE	1 kg	1	PHENOL	0.937 kg
		2	YELLOW PHOSPHORUS	0.10 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	20 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	018205001136AM20
RA File Number	052404000749 AM20
Licence No and Date	0510413850/12/03/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	21 / NC/3/MEET/Jan/202223/18			
Case Status	Case Rejected			
Party Name	GLOBAL CALCIUM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM REVIW00002534AM23			
RA File Number	072404000046 AM21			

Licence No and Date	0710116483/22/05/2020
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was observed that the reply furnished by the firm is not proper as they have attached papers of other licences / export products. Hence, it was decided to reject the case maintain the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	22 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00002538AM23
RA File Number	072404000053 AM21
Licence No and Date	0710116510/27/05/2020
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was observed that the reply furnished by the firm is incomplete. Hence, it was decided to reject the case maintaining the status quo. RA concerned may take further necessary action as per above decision of NC.	

Case No.	23 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	AMI ORGANICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM REVIW00004268AM23			
RA File Number	522404000013 AM21			
Licence No and Date	5210043424/08/06/2020			
Norms Committee Decision:				
The Committee considered the request of firm for fixation of adhoc norms and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

4-HYDROXY COUMARIN (by Acetyl Salicylic Acid route)	1 kg	1	Acetyl Salicylic Acid (For Industrial Use)	1.56 kg
		2	Ethyl Aceto Acetate	1.147 kg

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

Case No.	24 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	018205001409AM21
RA File Number	522404000018 AM21
Licence No and Date	5210043446/23/06/2020
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	25 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	VIBRANT PHARMACHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	018205001663AM21			
RA File Number	072404000163 AM21			
Licence No and Date	0710117014/15/09/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.

CIS TOSYLATE	1 kg	1	p-TOLUENESULFONYL CHLORIDE	2.066 kg
		2	IMIDAZOLE	1.380 kg

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

Case No.	26 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004093AM23
RA File Number	039404000283 AM21
Licence No and Date	0310838453/24/09/2020

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
COUMARIN	1 kg	1	PHENOL	1.15 kg
		2	XYLENE	0.50 kg
		3	MAGNESIUM TURNINGS	0.148 kg
		4	PARAFORMALDEHYDE	0.9177 kg
		5	ACETIC ANHYDRIDE	0.7356 kg

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

Case No.	27 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	018205001832AM21
RA File Number	052404000405 AM21
Licence No and Date	0510415761/06/11/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	28 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	018205001853AM21
RA File Number	342404000223 AM21
Licence No and Date	3410046549/13/11/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	29 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	018205001869AM21
RA File Number	052404000441 AM21
Licence No and Date	0510415972/24/11/2020
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	30 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00001578AM23
RA File Number	03AA04021189 AM21
Licence No and Date	0311001372/01/02/2021
Norms Committee Decision:	

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	ASHOXY 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack 100ML vial (EACH VIAL CONTAINS 38ML 2-pyrrolid(VETERINARY FORMULATION-INJECTION)	200000 Numbers	1	2 PYRROLIDONE	8000 kg
2	ASHOXY 20% LA (OXYTETRACYCLINE INJECTABLE SOLUTION 20% LONG ACTING) Pack 50ML vial (EACH VIAL CONTAINS 19ML 2-pyrrolido(VETERINARY FORMULATION-INJECTION)	323000 Numbers	2	2 PYRROLIDONE	6460 kg

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

Case No.	31 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	CHIRAG ENTERPRISE
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00076610AM21
RA File Number	24AA04002562 AM21
Licence No and Date	2411000202/04/02/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09/09/2022** against advance authorization No. **2410042868 dated 27.09.2019 and 2410042947 dated 12.12.2019**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
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CRUDE METHYL METHACRYLATE MONOMER	1 kg	1	ACRYLIC PLASTIC STRIPS / OFFCUTS	1.23 kg
Note: No repeat licence will be issued on the basis of above decision.				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	32 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00094103AM21
RA File Number	34AA04002716 AM21
Licence No and Date	3411000254/01/03/2021
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.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	33 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	VIBRANT PHARMACHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM APPLY 00000295AM22			
RA File Number	07AA04011201 AM21			
Licence No and Date	0711000825/01/04/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

CIS TOSYLATE (DRUG INTERMEDIATE)	1 kg	1	p-TOLUENESULFONYL CHLORIDE	2.066 kg
		2	IMIDAZOLE	1.380 kg

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

Case No.	34 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00004824AM22
RA File Number	05AA04000952 AM22
Licence No and Date	0511002092/06/04/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	35 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00023689AM22
RA File Number	07AA04002023 AM22
Licence No and Date	0711000922/21/04/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Production / Consumption data duly certified by GST.	

Case No.	36 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00027802AM22

RA File Number	07AA04002553 AM22
Licence No and Date	0711000992/27/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Production / Consumption data duly certified by GST.	

Case No.	37 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00027804AM22
RA File Number	07AA04002549 AM22
Licence No and Date	0711000993/27/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Production / Consumption data duly certified by GST.	

Case No.	38 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00027780AM22
RA File Number	07AA04000758 AM22
Licence No and Date	0711000991/27/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Dec/202223/15 dated 29/12/2022 against advance authorization No. 0711004325 dated 16/06/2022, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Export product	Qty.	Sl. No.	Import items	Qty.
MAGNESIUM BISGLYCINATE MAGNESIUM GLYCINE COMPLEX	/ 1 kg	1	GLYCINE	0.97 kg
		2	MAGNESIUM OXIDE	0.26 kg

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

Case No.	39 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	CLARIANT INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00032203AM22
RA File Number	03AA04009823 AM22
Licence No and Date	0311003530/04/05/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	40 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	CLARIANT INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00032203AM22
RA File Number	03AA04009823 AM22
Licence No and Date	0311003530/04/05/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	41 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00036355AM22
RA File Number	03AA04007493 AM22
Licence No and	0311003675/09/05/2021

Date	
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Complete chemistry with molecular weight of reactant and Product. ii. Percentage of Yield. By-Product and its value availing invoice.	

Case No.	42 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	MACLEODS PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00038818AM22
RA File Number	03AA04005126 AM22
Licence No and Date	0311003736/12/05/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No **NC/3/MEET/Nov/202223/14 dated 07/12/2022** against advance authorization No. **0311001091 dated 20/01/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 3080.240 kgs Dolutegravir Sodium + 18481.440 kgs Tenofovir Disoproxil Fumarate + 18481.440 kgs Lamivudine))	1 Number	1	(R)-3-AMINO-1-BUTANOL	19.635 mg
		2	1-(2,2-dimethoxyethyl)-5-methoxy-6(methoxycarbonyl) 4-oxo-1,4-dihydropyridine-3-carboxylic acid	Indigenously procured
		3	Lithium bromide anhydrous	Indigenously procured
		4	(R)-9-(2-phosphonomethoxy propyl)-adenine	205.02 mg
		5	LAMIVUDINE	Indigenously

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

Case No.	43 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	EAST AFRICAN INDIA OVERSEAS
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00039055AM22
RA File Number	05AA04009662 AM22
Licence No and Date	0511002560/12/05/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
NIPARIN 5ML(HEPARIN SODIUM INJECTION 5000 UNITS/ML)	33783 Numbers	1	HEPARIN SODIUM USP	900 MIU

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

Case No.	44 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00045345AM22
RA File Number	30AA04001247 AM22
Licence No and Date	3011000633/18/05/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
DEXKETOPROFFEN TROMETAMOL	1 kg	1	KETOPROFEN	1.00 kg
		2	N OCTYL D GLUCAMINE	0.36 kg
		3	TRIS AMINO BUFFER TROMETHAMINE	0.36 kg

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

Case No.	45 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00104366AM22
RA File Number	08AA04004876 AM22
Licence No and Date	0811001618/01/06/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Case No.	46 / NC/3/MEET/Jan/202223/18
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Case Status	Case Deferred
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00108212AM22
RA File Number	05AA04019922 AM22
Licence No and Date	0511002989/05/06/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: i. COA of Export Product. ii. COA of import item from foreign supplier. iii. Copy of Master Batch Formula.	

Case No.	47 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00109428AM22
RA File Number	34AA04002141 AM22
Licence No and Date	3411000701/08/06/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: i. Step wise manufacturing process. ii. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis iii. Stoichiometric balance between import and export on molar basis iv. Complete justification of wastage of raw materials for the manufacturing of export product.	

Case No.	48 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004186AM23
RA File Number	03AA04019330 AM22
Licence No and	0311004745/19/06/2021

Date	
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	49 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00122419AM22
RA File Number	34AA04003768 AM22
Licence No and Date	3411000762/23/06/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	50 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	ALKALOIDS CORPORATION			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM REVIW00004945AM23			
RA File Number	02AA04012158 AM22			
Licence No and Date	0211000889/05/07/2021			
Norms Committee Decision:				
The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jun/202223/5 dated 08/07/2022 against advance authorization No. 0210207287 dated 27/01/2017 , it was decided to revise adhoc norms as under:				

Case No.	51 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00135125AM22
RA File Number	30AA04009718 AM22
Licence No and Date	3011000867/09/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	52 / NC/3/MEET/Jan/202223/18				
Case Status	Case Approved				
Party Name	CERIGO ADDITIVES PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023				
HQ File Number	HQRNORM APPLY 00135220AM22				
RA File Number	03AA04027670 AM22				
Licence No and Date	0311005241/09/07/2021				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	CAP ADP-85 (2,2 Dithiobis N-Methylbenzamide)	1 kg	1	2 2 DITHIODIBENZOIC ACID	1.022 kg
2	CA Protect-100 (N-n-Butyl-1,2-Benzisothiazolin-3-one)	1 kg	2	2 2 DITHIODIBENZOIC ACID	1.329 kg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	53 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023

HQ File Number	HQRNORM APPLY 00136846AM22
RA File Number	34AA04005040 AM22
Licence No and Date	3411000829/12/07/2021
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	54 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00137048AM22
RA File Number	34AA04005105 AM22
Licence No and Date	3411000838/12/07/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Copy of DML for export item. ii. Complete chemistry, molecular weight, percentage yield on molar basis etc. as per Annexure to Appendix 4E.	

Case No.	55 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00137172AM22
RA File Number	08AA04014354 AM22
Licence No and Date	0811001969/12/07/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	Q PARIN 5000 IU/ML (Heparin Sodium) 5ML	1 Number	1	HEPARIN SODIUM BP (580 MEGA) (Potency 156.3 IU / mg)	175.944 mg
2	Q PARIN 1000 IU/ML (Heparin Sodium) 5ML	1 Number	2	HEPARIN SODIUM BP (580 MEGA) (Potency 156.3 IU / mg)	35.189 mg

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

Case No.	56 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00138116AM22
RA File Number	26AA04002063 AM22
Licence No and Date	2611000198/13/07/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	57 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00143924AM22
RA File Number	07AA04016516 AM22
Licence No and Date	0711001521/21/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Production / Consumption data duly certified by GST.	

Case No.	58 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	R.L.FINE CHEM PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00144695AM22
RA File Number	07AA04016662 AM22
Licence No and Date	0711001530/22/07/2021
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	59 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DIAMINES AND CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00145203AM22
RA File Number	34AA04005573 AM22
Licence No and Date	3411000885/22/07/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: (i) COA report of both import and export items giving clearly percentage of it purity. (ii) Production of export item vis-à-vis Consumption of all the raw materials (both imported and indigenous)) for last three years duly certified by GST / CA. (iii) Total sales value of By-Product per kg of export item, giving evidence and also to subtract the quantity of import item per kg of export from this value.	

Case No.	60 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SYNOKEM PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00147457AM22
RA File Number	05AA04059070 AM22
Licence No and Date	0511003826/26/07/2021
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	61 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00148635AM22
RA File Number	07AA04017973 AM22
Licence No and Date	0711001565/27/07/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **10/82-ALC4/2018 dated 16/10/2018** against advance authorization No. **0710112770 dated 02/02/2018**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
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.	62 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	ZEE LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00149067AM22
RA File Number	05AA04057371 AM22
Licence No and Date	0511003868/28/07/2021

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.

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

Case No.	63 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00150875AM22
RA File Number	05AA04055660 AM22
Licence No and Date	0511003910/30/07/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information:	
(i) Copy of DML for export item showing Approved Composition. (ii) COA of the export item. (iii) Process details with wastage claimed.	

Case No.	64 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004039AM23
RA File Number	34AA04005924 AM22
Licence No and Date	3411000924/02/08/2021
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information:	
i. Complete justification for low yield giving chemistry. ii. Production / Consumption data duly certified by GST.	

Case No.	65 / NC/3/MEET/Jan/202223/18
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Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004041AM23
RA File Number	34AA04005925 AM22
Licence No and Date	3411000923/02/08/2021
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee for explaining its case alongwith following documents / information: i. Step wise manufacturing process. ii. Complete chemical reactions with molecular and structural formula and molecular weights alongwith stage wise percentage yields on molar basis. iii. Complete technical details as per Annexure to Appendix 4E for chemical products. iv. Stoichiometric balance between import and export on molar basis.	

Case No.	66 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00397057AM22
RA File Number	08AA04017921 AM22
Licence No and Date	0811002234/04/08/2021
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and as per the following details furnished by the firm: i. As per the COA furnished by the firm from foreign supplier, content of Triflow Acetic Acid varies from 8% to 12% besides 1.7% water and other Residual solvents to compensate 12.34% excess API is used. Bivaludin Free Base is otherwise unstable as an API. 11.71%. ii. 11.71% wastage is shown for manufacturing Process Loss. iii. Since the export product is Freeze Dried Powder, 12% excess volume is added as per regulatory requirement.	

(iv) Export to USA and Canada only.

Considering 12.34% Potency loss, 10% standard manufacturing loss as per SION and 2% notional extra-filling, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
BIVALIRUDIN FOR INJECTION 250 MG/VIAL (5ML VIAL) (Freeze Dried Powder for Injection 250 mg / Vial) (EACH VIAL CONTAINS: BIVALIRUDIN 250 MG	1 Number	1	Bivalirudin (containing 8% to 12% Triflow Acetic Acid as per COA)	315.114 mg/ Vial

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

Case No.	67 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00397079AM22
RA File Number	08AA04018916 AM22
Licence No and Date	0811002280/09/08/2021

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and considering potency correction due to all Alcoholic Solvents and water content not less than 1.86% as per COA furnished by the firm, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
NALTREXONE HYDROCHLORIDE TABLETS 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE	1 Number	1	NALTREXONE HYDROCHLORIDE EP / BP / IP / USP / PH. EUR (All Alcoholic Solvents and water content NLT 1.86% as per COA of import item)	51.93 mg / Tablet

HYDROCHLORIDE PH. EUR. 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 135.000 KGS.)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	68 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00170502AM22
RA File Number	08AA04022482 AM22
Licence No and Date	0811002393/25/08/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	69 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00397092AM22
RA File Number	08AA04023464 AM22
Licence No and Date	0811002450/31/08/2021
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and considering potency correction due to all Alcoholic Solvents and water content not less than 1.86% as per COA furnished by the firm, it was decided to revise adhoc norms as under:	

TABLET CONTAINS: NALTREXONE			per COA of import item)	
HYDROCHLORIDE PH. EUR. 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 135.000 KGS.)]				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	70 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00001475AM23
RA File Number	08AA04022429 AM22
Licence No and Date	0811002501/06/09/2021

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and as per the following details furnished by the firm:

- i. As per the COA furnished by the firm from foreign supplier, content of Triflow Acetic Acid varies from 8% to 12% besides 1.7% water and other Residual solvents to compensate 12.34% excess API is used. Bivaludin Free Base is otherwise unstable as an API. 11.71%.
- ii. 11.71% wastage is shown for manufacturing Process Loss.
- iii. Since the export product is Freeze Dried Powder, 12% excess volume is added as per regulatory requirement.
- (iv) Export to USA and Canada only.

Considering 12.34% Potency loss, 10% standard manufacturing loss as per SION and 2% notional extra-filling, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
BIVALIRUDIN FOR INJECTION 250 MG/VIAL (5ML VIAL) (Freeze Dried Powder for Injection 250 mg / Vial) (EACH VIAL CONTAINS: BIVALIRUDIN 250 MG	1 Number	1	Bivalirudin (containing 8% to 12% Triflow Acetic Acid as per COA)	315.114 mg/Vial

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

Case No.	71 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00177562AM22
RA File Number	08AA04023793 AM22
Licence No and Date	0811002515/06/09/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. DML ii. Master Batch Formula.	

Case No.	72 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00397104AM22
RA File Number	08AA04025507 AM22
Licence No and Date	0811002517/06/09/2021
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and as per the following details furnished by the firm:	

i. As per the COA furnished by the firm from foreign supplier, content of Triflow Acetic Acid varies from 8% to 12% besides 1.7% water and other Residual solvents to compensate 12.34% excess API is used. Bivaludin Free Base is otherwise unstable as an API. 11.71%.

ii. 11.71% wastage is shown for manufacturing Process Loss.

iii. Since the export product is Freeze Dried Powder, 12% excess volume is added as per regulatory requirement.

(iv) Export to USA and Canada only.

Considering 12.34% Potency loss, 10% standard manufacturing loss as per SION and 2% notional extra-filling, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
BIVALIRUDIN FOR INJECTION 250 MG/VIAL (5ML VIAL) (Freeze Dried Powder for Injection 250 mg / Vial) (EACH VIAL CONTAINS: BIVALIRUDIN 250 MG	1 Number	1	Bivalirudin (containing 8% to 12% Triflow Acetic Acid as per COA)	315.114 mg/ Vial

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

Case No.	73 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00177945AM22
RA File Number	05AA04070230 AM22
Licence No and Date	0511004557/06/09/2021

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.

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

Case No.	74 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00178977AM22
RA File Number	08AA04026034 AM22
Licence No and Date	0811002528/07/09/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	75 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00179705AM22
RA File Number	05AA04071036 AM22
Licence No and Date	0511004601/08/09/2021
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.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	76 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00181385AM22
RA File Number	08AA04024263 AM22
Licence No and Date	0811002550/10/09/2021
Norms Committee Decision:	

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

- i. **DML.**
- ii. **Master Batch Formula.**
- iii. **COA of import item from foreign supplier.**
- iv. **Composition of import item.**

Case No.	77 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00181607AM22
RA File Number	05AA04061713 AM22
Licence No and Date	0511004657/10/09/2021
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	78 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DIAMINES AND CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00184161AM22
RA File Number	34AA04007354 AM22
Licence No and Date	3411001111/15/09/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: i. COA report of both import and export items giving clearly percentage of it purity. ii. Production of export item vis-à-vis Consumption of all the raw materials (both imported and indigenous)) for last three years duly certified by GST / CA. iii. Total sales value of By-Product per kg of export item, giving evidence and also to subtract the quantity of import item per kg of export from this value.	

Case No.	79 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00184484AM22
RA File Number	05AA04076999 AM22
Licence No and Date	0511004742/15/09/2021
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	80 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SANOFI INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00185047AM22
RA File Number	03AA04082679 AM22
Licence No and Date	0311007007/16/09/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	81 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00185767AM22
RA File Number	03AA04011760 AM22
Licence No and Date	0311007030/16/09/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Export product	Qty.	Sl. No.	Import items	Qty.
Atorvastatin Calcium USP / BP / EP	1 kg	1	(4R-CIS)-1, 1- Dimethylethyl-6-Cyanomethyl-2, 2-Dimethyl-1-3-Dioxane-4-Acetate	0.708 kg
		2	Iso Propyl Alcohol	2.56 kg
		3	Methanol	4.285 kg

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

Case No.	82 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00187904AM22
RA File Number	08AA04029099 AM22
Licence No and Date	0811002644/20/09/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	83 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00187990AM22
RA File Number	07AA04024759 AM22
Licence No and Date	0711001935/20/09/2021
Norms Committee Decision:	
The firm vide its e-mail dated 10.02.2023 has requested to grant them time to submit its reply.	
The Committee considered the request of firm and it was decided to grant them 15 days time to firm to furnish its reply.	

Case No.	84 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00001473AM23
RA File Number	08AA04029213 AM22
Licence No and Date	0811002696/27/09/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	85 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00195372AM22
RA File Number	34AA04006808 AM22
Licence No and Date	3411001180/27/09/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case.	

Case No.	86 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00201651AM22
RA File Number	07AA04031322 AM22
Licence No and Date	0711002073/04/10/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Complete technical details as per Annexure to Appendix 4E.	

Case No.	87 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred

Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00201659AM22
RA File Number	07AA04034939 AM22
Licence No and Date	0711002076/04/10/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Complete technical details as per Annexure to Appendix 4E. ii. Technical literature in support of yield. iii. Production / Consumption data duly certified by GST.	

Case No.	88 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	INTAS PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM REVIW00397111AM22			
RA File Number	08AA04030678 AM22			
Licence No and Date	0811002770/04/10/2021			
Norms Committee Decision:				
The Committee considered the request of firm for review of adhoc norms and considering potency correction due to all Alcoholic Solvents and water content not less than 1.86% as per COA furnished by the firm, it was decided to revise adhoc norms as under:				
Export product	Qty.	Sl. No.	Import items	Qty.
NALTREXONE HYDROCHLORIDE TABLETS 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE PH. EUR. 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 135.000 KGS.])	1 Number	1	NALTREXONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR (All Alcoholic Solvents and water content NLT 1.86% as per COA of import item)	51.93 mg / Tablet

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

Case No.	89 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	KRITI NUTRIENTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00210670AM22
RA File Number	56AA04005794 AM22
Licence No and Date	5611000556/12/10/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: (i) Complete specification and COA of import item from foreign supplier. (ii) Point out the difference in specification of import and export. (iii) Production / Consumption data for last two years duly certified by GST.	

Case No.	90 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	KRITI NUTRIENTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00210670AM22
RA File Number	56AA04005794 AM22
Licence No and Date	5611000556/12/10/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: (i) Complete specification and COA of import item from foreign supplier. (ii) Point out the difference in specification of import and export. (iii) Production / Consumption data for last two years duly certified by GST	

Case No.	91 / NC/3/MEET/Jan/202223/18
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Case Status	Case Approved													
Party Name	BENZO CHEM INDUSTRIES PVT LTD													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00211526AM22													
RA File Number	03AA040110500 AM22													
Licence No and Date	0311007683/13/10/2021													
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No NC/3/MEET/Sep/202223/9 dated 07/10/2022 against advance authorization No. 0311012331 dated 07/03/2022, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: <table border="1"> <thead> <tr> <th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> <tr> <td rowspan="2">2-AMINO -2-PHENYLBUTYRIC ACID SODIUM SALT</td><td rowspan="2">1 kg</td><td>1</td><td>PROPIOPHENONE</td><td>0.922 kg</td></tr> <tr> <td>2</td><td>SODIUM CYANIDE (NaCN)</td><td>0.337 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.	2-AMINO -2-PHENYLBUTYRIC ACID SODIUM SALT	1 kg	1	PROPIOPHENONE	0.922 kg	2	SODIUM CYANIDE (NaCN)	0.337 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
2-AMINO -2-PHENYLBUTYRIC ACID SODIUM SALT	1 kg	1	PROPIOPHENONE	0.922 kg										
		2	SODIUM CYANIDE (NaCN)	0.337 kg										

Case No.	92 / NC/3/MEET/Jan/202223/18					
Case Status	Case Approved					
Party Name	EAST AFRICAN INDIA OVERSEAS					
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023					
HQ File Number	HQRNORM APPLY 00211838AM22					
RA File Number	05AA04081672 AM22					
Licence No and Date	0511005408/13/10/2021					
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: <table border="1"> <thead> <tr> <th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> </tbody> </table>		Export product	Qty.	Sl. No.	Import items	Qty.
Export product	Qty.	Sl. No.	Import items	Qty.		

Aziriv Tablet 500 mg (AZITHROMYCIN TABLETS 500 MG)	1 Number	1	AZITHROMYCIN Dihydrate USP	534.512 mg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	93 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00001474AM23
RA File Number	08AA04033170 AM22
Licence No and Date	0811002920/20/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	94 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00001209AM23
RA File Number	08AA04033169 AM22
Licence No and Date	0811002929/20/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	95 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00001519AM23
RA File Number	31AA04028264 AM22
Licence No and Date	3111000632/21/10/2021
Norms Committee Decision:	

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

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

Case No.	96 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00221594AM22
RA File Number	08AA04033661 AM22
Licence No and Date	0811002958/22/10/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	97 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	METROPOLITAN EXIMCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00225235AM22
RA File Number	03AA040108347 AM22
Licence No and Date	0311007901/25/10/2021
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.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	98 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	METROPOLITAN EXIMCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00225235AM22
RA File Number	03AA040108347 AM22
Licence No and	0311007901/25/10/2021

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

Case No.	99 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	INTAS PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM REVIW00000529AM23			
RA File Number	08AA04033768 AM22			
Licence No and Date	0811002982/26/10/2021			
Norms Committee Decision:				
The Committee considered the request of firm for review of adhoc norms and considering potency correction due to all Alcoholic Solvents and water content not less than 1.86% as per COA furnished by the firm, it was decided to revise adhoc norms as under:				
Export product	Qty.	Sl. No.	Import items	Qty.
NALTREXONE HYDROCHLORIDE TABLETS 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE PH. EUR. 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 135.000 KGS.])	1 Number	1	NALTREXONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR (All Alcoholic Solvents and water content NLT 1.86% as per COA of import item)	51.93 mg / Tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	100 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM REVIW00000528AM23													
RA File Number	08AA04034748 AM22													
Licence No and Date	0811003137/15/11/2021													
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and considering potency correction due to all Alcoholic Solvents and water content not less than 1.86% as per COA furnished by the firm, it was decided to revise adhoc 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.</th> </tr> </thead> <tbody> <tr> <td> NALTREXONE HYDROCHLORIDE TABLETS 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE PH. EUR. 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 135.000 KGS.]) </td> <td>1 Number</td> <td>1</td> <td> NALTREXONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR (All Alcoholic Solvents and water content NLT 1.86% as per COA of import item) </td> <td>51.93 mg / Tablet</td> </tr> </tbody> </table>					Export product	Qty.	Sl. No.	Import items	Qty.	NALTREXONE HYDROCHLORIDE TABLETS 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE PH. EUR. 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 135.000 KGS.])	1 Number	1	NALTREXONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR (All Alcoholic Solvents and water content NLT 1.86% as per COA of import item)	51.93 mg / Tablet
Export product	Qty.	Sl. No.	Import items	Qty.										
NALTREXONE HYDROCHLORIDE TABLETS 50 MG(EACH FILM COATED TABLET CONTAINS: NALTREXONE HYDROCHLORIDE PH. EUR. 50 MG [IN WHICH ACTIVE INGREDIENT NALTREXONE HYDROCHLORIDE USED IS 135.000 KGS.])	1 Number	1	NALTREXONE HYDROCHLORID E EP / BP / IP / USP / PH. EUR (All Alcoholic Solvents and water content NLT 1.86% as per COA of import item)	51.93 mg / Tablet										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	101 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00000530AM23
RA File Number	08AA04034735 AM22
Licence No and Date	0811003139/15/11/2021
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and as per the following details furnished by the firm: i. As per the COA furnished by the firm from foreign supplier, content of Triflow Acetic Acid varies from 8% to 12%	

besides 1.7% water and other Residual solvents to compensate 12.34% excess API is used. Bivaludin Free Base is otherwise unstable as an API. 11.71%.

ii. 11.71% wastage is shown for manufacturing Process Loss.

iii. Since the export product is Freeze Dried Powder, 12% excess volume is added as per regulatory requirement.

(iv) Export to USA and Canada only.

Considering 12.34% Potency loss, 10% standard manufacturing loss as per SION and 2% notional extra-filling, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
BIVALIRUDIN FOR INJECTION 250 MG/VIAL (5ML VIAL) (Freeze Dried Powder for Injection 250 mg / Vial) (EACH VIAL CONTAINS: BIVALIRUDIN 250 MG	1 Number	1	Bivalirudin (containing 8% to 12% Triflow Acetic Acid as per COA)	315.114 mg/ Vial

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

Case No.	102 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00262416AM22
RA File Number	34AA04008408 AM22
Licence No and Date	3411001440/23/11/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	

Actual quantity with its value of each By-Product produced per MT of Export Product manufacturing.

Case No.	103 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00262416AM22
RA File Number	34AA04008408 AM22
Licence No and Date	3411001440/23/11/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Actual quantity with its value of each By-Product produced per MT of Export Product manufacturing.	

Case No.	104 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00263488AM22
RA File Number	03AA04014060 AM22
Licence No and Date	0311008817/24/11/2021
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	105 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00263488AM22
RA File Number	03AA04014060 AM22
Licence No and Date	0311008817/24/11/2021

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.

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

Case No.	106 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00263483AM22
RA File Number	03AA04003343 AM22
Licence No and Date	0311008815/24/11/2021

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.

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

Case No.	107 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00263483AM22
RA File Number	03AA04003343 AM22
Licence No and Date	0311008815/24/11/2021

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.

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

Case No.	108 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023

and Date	
HQ File Number	HQRNORM APPLY 00263486AM22
RA File Number	03AA04009051 AM22
Licence No and Date	0311008816/24/11/2021
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.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	109 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00263486AM22
RA File Number	03AA04009051 AM22
Licence No and Date	0311008816/24/11/2021
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.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	110 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00266181AM22
RA File Number	08AA04035102 AM22
Licence No and Date	0811003242/26/11/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	111 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SUDEEP PHARMA PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00270155AM22
RA File Number	342404000285 AM20
Licence No and Date	3411001477/30/11/2021
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	112 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00270155AM22
RA File Number	342404000285 AM20
Licence No and Date	3411001477/30/11/2021
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	113 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00271633AM22
RA File Number	342404000080 AM21
Licence No and Date	3411001485/01/12/2021
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.	

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

Case No.	114 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	UPL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00271160AM22
RA File Number	03AA040125862 AM22
Licence No and Date	0311009068/01/12/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202223/15 dated 29/12/2022** against advance authorization No. **03110015330 dated 08/06/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Tri phenyl Phosphite	1 kg	1	Phenol	0.937 kg
		2	Yellow Phosphorus	0.10 kg

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

Case No.	115 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00271471AM22
RA File Number	342404000079 AM21
Licence No and Date	3411001482/01/12/2021

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.

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

Case No.	116 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00271583AM22
RA File Number	342404000002 AM21
Licence No and Date	3411001484/01/12/2021
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	117 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	PMC RUBBER CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00272783AM22
RA File Number	02AA04035173 AM22
Licence No and Date	0211001583/02/12/2021
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	118 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00272834AM22
RA File Number	03AA04014502 AM22
Licence No and Date	0311009117/02/12/2021

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.

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

Case No.	119 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00272951AM22
RA File Number	03AA04014150 AM22
Licence No and Date	0311009127/02/12/2021

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.

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

Case No.	120 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ASHISH LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00276162AM22
RA File Number	03AA040123869 AM22
Licence No and Date	0311009212/06/12/2021

Norms Committee Decision:

Deferred for comments of TE.

Case No.	121 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SHIVAM ADDITIVES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00001552AM23
RA File Number	13AX04000009 AM22
Licence No and	1311000821/15/12/2021

Date	
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	122 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00289566AM22
RA File Number	34AX04000036 AM22
Licence No and Date	3411001553/17/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: i. Step wise manufacturing process. ii. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis iii. Stoichiometric balance between import and export on molar basis iv. Complete justification of wastage of raw materials for the manufacturing of export product.	

Case No.	123 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00289569AM22
RA File Number	34AX04000035 AM22
Licence No and Date	3411001554/17/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: i. Step wise manufacturing process.	

- ii. **Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis**
- iii. **Stoichiometric balance between import and export on molar basis.**
- iv. **Complete justification of wastage of raw materials for the manufacturing of export product.**

Case No.	124 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00291533AM22
RA File Number	34AX04000052 AM22
Licence No and Date	3411001560/20/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. DML for each export Product ii. Master Batch Formula for each export product.	

Case No.	125 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	MELZER CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00291926AM22
RA File Number	31AA04030064 AM22
Licence No and Date	3111000802/20/12/2021
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	126 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023

HQ File Number	HQRNORM APPLY 00291474AM22
RA File Number	08AX04000083 AM22
Licence No and Date	0811003487/20/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	127 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00293146AM22
RA File Number	34AX04000029 AM22
Licence No and Date	3411001569/21/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	128 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00298292AM22
RA File Number	08AX04000091 AM22
Licence No and Date	0811003537/27/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	129 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00298304AM22
RA File Number	05AX04000086 AM22
Licence No and Date	0511007243/27/12/2021
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.

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

Case No.	130 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SAVLA CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00298647AM22
RA File Number	03AX04000385 AM22
Licence No and Date	0311009839/27/12/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	131 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00299896AM22
RA File Number	34AX04000090 AM22
Licence No and Date	3411001598/28/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. DML for each export Product. ii. Master Batch Formula for each export product.	

Case No.	132 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	PI INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004300AM23
RA File Number	13AX04000083 AM22
Licence No and Date	1311001018/17/02/2022

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
PIA - 4 Chemical Name: 3-(bromomethyl)-2-chloro-4-(methylsulfonyl)benzoic acid	1 kg	1	3-Chloro -2-Methyl aniline	0.625 kg
		2	Sodium Nitrite	0.366 kg
		3	Sodium Methyl Mercaptide	1.570 kg
		4	Bromine	0.634 kg

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

Case No.	133 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00359783AM22
RA File Number	34AX04000191 AM22
Licence No and Date	3411001829/18/02/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Actual quantity with its value of each By-Product produced per MT of Export Product manufacturing.	

Case No.	134 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00359728AM22
RA File Number	08AX04000474 AM22

Licence No and Date	0811004112/18/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	135 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00367121AM22
RA File Number	03AX04001357 AM22
Licence No and Date	0311011780/25/02/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202223/15 dated 29/12/2022** against advance authorization No. **0311015585 dated 16/06/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Ciprofloxacin and Dexamethasone Suspension USP (0.3 / 0.1 percentage) 7.5ml Bottle.((Each ml Contains:CIPROFLOXACIN HYDROCHLORIDE EQU TO CIPROFLOXACIN BASE 3mg and DEXAMETHASONE 1mg per bottle of 7.5ml) (Each 7.5 ml Contains: Ciprofloxacin 22.5mg & Dexamethasone 7.5 mg) Net wt. Ciprofloxacin HCL 15.750kgs & Dexamethasone 5.250kgs)	700000 Numbers	1	Ciprofloxacin HCL	18.113 kg
		2	Dexamethasone	5.513 kg
		3	Bottle	Relevant as per packing policy
		4	Cap	Relevant as per packing policy
		5	Dropper	Relevant as per packing policy

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

Case No.	136 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00367304AM22
RA File Number	09AX04000261 AM22
Licence No and Date	0911002566/25/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	137 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00367536AM22
RA File Number	08AX04000483 AM22
Licence No and Date	0811004214/25/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	138 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00367541AM22
RA File Number	08AX04000478 AM22
Licence No and Date	0811004216/25/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	139 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00367543AM22
RA File Number	08AX04000490 AM22
Licence No and Date	0811004217/25/02/2022
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	140 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00370625AM22
RA File Number	34AX04000311 AM22
Licence No and Date	3411001873/28/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Actual quantity with its value of each By-Product produced per MT of Export Product manufacturing.	

Case No.	141 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	HIMADRI SPECIALITY CHEMICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00372545AM22
RA File Number	02AX04000172 AM22
Licence No and Date	0211002041/02/03/2022
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. RA concerned may take further necessary action as per above decision of NC.	

Case No.	142 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	SAKAR HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00375600AM22
RA File Number	08AX04000616 AM22
Licence No and Date	0811004272/04/03/2022

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.

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

Case No.	143 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00379532AM22
RA File Number	08AX04000605 AM22
Licence No and Date	0811004316/08/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	144 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00380949AM22
RA File Number	34AX04000157 AM22
Licence No and Date	3411001935/09/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	145 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00004872AM23
RA File Number	03AX04002100 AM22
Licence No and Date	0311013612/05/04/2022
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and it was decided to revise adhoc norms as	

under:

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty.
1	Atorvastatin Calcium Tablets USP 10mg((Pack Size 90 tabs) (Net wt. of Import Sr. No. 1 is 793.512kgs, Sr. No. 2 is 4394.736kg, Sr. No. 3 is 1247.976kg, Sr. No. 5 is 808000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			4	Strippax Sorbent 50 C & 50 SG 2gm (Silica Gel Dessicants)	Relevant as per packing policy
2	Atorvastatin Calcium Tablets USP 10mg((Pack Size 1000 tabs) (Net wt. of Import Sr. No. 1 is 826.575kgs, Sr. No. 2 is 4577.85kg, Sr. No. 3 is 1299.975kg, Sr. No. 5 is 75750 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			4	Strippax Sorbent 50 C & 50 SG 2gm (Silica Gel Dessicants)	Relevant as per packing policy
3	Atorvastatin Calcium Tablets USP 20mg((Pack Size 90 tabs) (Net wt. of Import Sr. No. 1 is 148.784kgs, Sr. No. 2 is 826.929kg, Sr. No. 3 is 234.698kg, Sr. No. 5 is 75750 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427 mg
			3	Calcium Acetate	36.090 mg
			4	Strippax Sorbent 50 C & 50 SG 2gm (Silica Gel Dessicants)	Relevant as per packing policy
4	Atorvastatin Calcium Tablets USP 40mg((Pack Size 90 tabs)	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg

	(Net wt. of Import Sr. No. 1 is 2023.456kgs, Sr. No. 2 is 11207.403kg, Sr. No. 3 is 3182.522kg, Sr. No. 5 is 515100 Nos.))		2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08 mg
			3	Calcium Acetate	71.963 mg
			4	Strippax Sorbent 50 C & 50 SG 2gm (Silica Gel Dessicants)	Relevant as per packing policy
5	Atorvastatin Calcium Tablets USP 40mg((Pack Size 1000 tabs) (Net wt. of Import Sr. No. 1 is 2055.196kgs, Sr. No. 2 is 11383.205kg, Sr. No. 3 is 3232.444kg, Sr. No. 5 is 47086 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08 mg
			3	Calcium Acetate	71.963 mg
			4	Strippax Sorbent 50 C & 50 SG 2gm (Silica Gel Dessicants)	Relevant as per packing policy
6	Atorvastatin Calcium Tablets USP 80mg((Pack Size 90 tabs) (Net wt. of Import Sr. No. 1 is 1658.44kgs, Sr. No. 2 is 9229.86kg, Sr. No. 3 is 2619.048kg, Sr. No. 4 is 211090 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			4	Strippax Sorbent 50 C & 50 SG 2gm (Silica Gel Dessicants)	Relevant as per packing policy
7	Atorvastatin Calcium Tablets USP 80mg((Pack Size 1000 tabs) (Net wt. of Import Sr. No. 1 is 1908.837kgs, Sr. No. 2 is 10623.417kg, Sr. No. 3 is 3014.481kg, Sr. No. 4 is 21867 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			4	Strippax Sorbent 50 C & 50 SG 2gm (Silica Gel Dessicants)	Relevant as per packing policy

Note: The above norms are valid only for subject to fulfillment of following conditions:

1. **Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application) of Apotex Corp, US. Agent for Apotex Inc., Candada.**
2. **Export to USA only.**
3. **Firm holding Certificate of Manufacturing Exclusivity.**

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

Case No.	146 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM REVIW00005043AM23
RA File Number	05AX04000321 AM23
Licence No and Date	0511012512/12/05/2022

Norms Committee Decision:

The Committee considered the request of firm for review of norms and on the basis of written comments furnished by Department of Biotechnology vide D.O. Letter No. PID-13011(15)/1/2021-PPB-DBT dated 02.01.2023, it was decided to revise norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
Easy Five TT Vaccine DTwP-Hep B-Hib-Pentavalent Vaccine (Each vial of 0.5 ml contains 1 dose)	1 Million Vials	1	Purified Diptheria Toxoid Concentrate Antigen Bulk @2050 Lf/ml	13.33 Litre
		2	Purified Tetanus Toxoid Concentrate Antigen @1900 Lf/ml	5.23 Litre
		3	Inactivated Whole Cell Pertussis Bulk @192 OU/ml	86.46 Litre
		4	Rubber Stopper	1010000 Numbers
		5	AGS HB Purification MABS Column	5.4 Litre

		6	Tetanus Toxoid for conjugation	6.15 Litre
		7	VVM Dot 14	1015000 Numbers

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

Case No.	147 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002443AM23
RA File Number	07AX04000653 AM23
Licence No and Date	0711004832/03/08/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Production / Consumption data duly certified by GST.	

Case No.	148 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	JODAS EXPOIM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM APPLY 00002494AM23			
RA File Number	09AX04000207 AM23			
Licence No and Date	0911003443/05/08/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/202122/8 dated 24/09/2021 against advance authorization No. 0910068207 dated 20/11/2019 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.

Ertapenem for Injection 1 gram/ vial (Net content of the import item is 66.666 Kgs)	1 Number	1	ERTAPENEM SODIUM	1.10 gram
RA concerned may take further necessary action as per above decision of NC.				

Case No.	149 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002596AM23
RA File Number	34AX04000442 AM23
Licence No and Date	3411002639/11/08/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Actual quantity with its value of each By-Product produced per MT of Export Product manufacturing.	

Case No.	150 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	GUJARAT FLUOROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002598AM23
RA File Number	34AX04000342 AM23
Licence No and Date	3411002640/11/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	151 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	MEGHMANI FINECHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002599AM23
RA File Number	34AX04000456 AM23

Licence No and Date	3411002641/11/08/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Stoichiometric balance on molar basis between import and export. ii. Complete chemical reaction with molecular and structural formula and molecular weight alongwith stage wise percentage yield on molar basis.	

Case No.	152 / NC/3/MEET/Jan/202223/18													
Case Status	Case Approved													
Party Name	ENALTEC LABS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00002600AM23													
RA File Number	03AX04002611 AM23													
Licence No and Date	0311017117/11/08/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. 4/82-ALC4/2018 dated 19/06/2018 against advance authorization No. 0310818572 dated 17/01/2018 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Rosuvastatin Calcium (R-10 Route)</td><td>1 kg</td><td>1</td><td>6-[(1E)-2-[4-(4-Fluorophenyl)-6-(1-Methylethyl)-2-[Methyl(Methylsulfonyl)Amino]-5-Pyrimidinyl]Ethenyl]-2,2-Dimethyl-1,3-Dioxane-4-Acetic Acid 1,1-Dimethylethyl Ester</td><td>1.30 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	Rosuvastatin Calcium (R-10 Route)	1 kg	1	6-[(1E)-2-[4-(4-Fluorophenyl)-6-(1-Methylethyl)-2-[Methyl(Methylsulfonyl)Amino]-5-Pyrimidinyl]Ethenyl]-2,2-Dimethyl-1,3-Dioxane-4-Acetic Acid 1,1-Dimethylethyl Ester	1.30 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Rosuvastatin Calcium (R-10 Route)	1 kg	1	6-[(1E)-2-[4-(4-Fluorophenyl)-6-(1-Methylethyl)-2-[Methyl(Methylsulfonyl)Amino]-5-Pyrimidinyl]Ethenyl]-2,2-Dimethyl-1,3-Dioxane-4-Acetic Acid 1,1-Dimethylethyl Ester	1.30 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	153 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	MAIVA PHARMA PRIVATE LIMITED			
Meeting Number	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			

and Date				
HQ File Number	HQRNORM APPLY 00002606AM23			
RA File Number	07AX04000675 AM23			
Licence No and Date	0711004873/11/08/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Dec/202223/15 dated 29/12/2022 against advance authorization No. 0711004432 dated 28/06/2022, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Prochlorperazine Edisylate Injection 10mg/ 2mL (Prochlorperazine Edisylate Injection 10mg, 2mL vial - 10 mg of bulk drug filled in 2 mL vial and capped with 13mm Rubber Stopper & 13mm Omniflexplus Coated(Dark Grey) Seals)	1 Number	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
RA concerned may take further necessary action as per above decision of NC.				

Case No.	154 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	FDC LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM APPLY 00002637AM23			
RA File Number	03AX04002596 AM23			
Licence No and Date	0311017156/12/08/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
GENTAMICIN EYE/EAR DROPS	187000	1	GENTAMICIN SULPHATE	5.722 kg

10ML(GENTAMICIN EYE/EAR DROPS 10ML (EACH VIAL CONTAINS GENTAMICIN SULPHATE 0.030 GM NET WT OF A BULK DRUG IS 5.610 KGS))	Vials			
RA concerned may take further necessary action as per above decision of NC.				

Case No.	155 / NC/3/MEET/Jan/202223/18										
Case Status	Case Approved										
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023										
HQ File Number	HQRNORM APPLY 00002638AM23										
RA File Number	31AX04000146 AM23										
Licence No and Date	3111001620/12/08/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Gliclazide BP</td><td>1 kg</td><td>1</td><td>N-Amino-3-azabicyclo (3,3.0) Octane HCL</td><td>0.577 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Gliclazide BP	1 kg	1	N-Amino-3-azabicyclo (3,3.0) Octane HCL	0.577 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
Gliclazide BP	1 kg	1	N-Amino-3-azabicyclo (3,3.0) Octane HCL	0.577 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	156 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002625AM23
RA File Number	34AX04000448 AM23
Licence No and Date	3411002646/12/08/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending <u>Personal Hearing</u> before Norms Committee for explaining its case.	

Case No.	157 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	KEVA FRAGRANCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002634AM23
RA File Number	03AX04002522 AM23
Licence No and Date	0311017151/12/08/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Chemical name and complete COA of import and export item. ii. Quantity of By-Products obtained and their commercial value. iii. Production / Consumption data for last two years duly certified by GST.	

Case No.	158 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	MEGHMANI FINECHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002655AM23
RA File Number	34AX04000449 AM23
Licence No and Date	3411002647/16/08/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Stoichiometric balance on molar basis between import and export. ii. Complete chemical reaction with molecular and structural formula and molecular weight alongwith stage wise percentage yield on molar basis.	

Case No.	159 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002656AM23
RA File Number	09AX04000230 AM23
Licence No and Date	0911003485/16/08/2022

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
LEVETIRACETAM	1 kg	1	S(+)-2-Amino butyramide hydrochloride	0.95 kg
		2	Methylene Chloride	2.26 kg
		3	Acetone	0.40 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	160 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002645AM23
RA File Number	03AX04002727 AM23
Licence No and Date	0311017254/16/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	161 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002657AM23
RA File Number	05AX04001367 AM23
Licence No and Date	0511014295/16/08/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import	

item in Meeting No. **NC/3/MEET/Apr/202223/1 dated 29/04/2022** against advance authorization No. **0511006792 dated 10/12/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Brinex / Brinex-M / Brinarga / Brinera (Brinzolamide Ophthalmic Suspension 1%)- 5ml	1 Vial	1	Brinzolamide	51.00 mg / Vial

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

Case No.	162 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002646AM23
RA File Number	03AX04002728 AM23
Licence No and Date	0311017256/16/08/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Oct/202122/9 dated 15/10/2021** against advance authorization No. **0310838214 dated 11/09/2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Clindamycin & Benzoyl Peroxide Gel 1percent/5percent (Pack Size 25gm Pack) (Net Wt. of Import Item Sr. No. 1 is 25.00 Kgs. & Sr. No. 2 is 125.00 Kgs.))	1 Number	1	Clindamycin Phosphate USP	262.50 mg / pack
			2	HYDROUS BENZOYL PEROXIDE USP	1312.50 mg / pack
2	Clindamycin & Benzoyl Peroxide Gel 1percent/5percent (Pack Size 35gm Pack) (Net Wt. of Import Item Sr. No. 1 is 35.00 Kgs. & Sr. No. 2 is 175.00 Kgs.))	1 Number	1	Clindamycin Phosphate USP	367.50 mg / pack
			2	HYDROUS BENZOYL PEROXIDE USP	1837.50 mg / pack

				PEROXIDE USP	pack
3	Clindamycin & Benzoyl Peroxide Gel 1percent/5percent (Pack Size 50gm Pack) ((Net Wt. of Import Item Sr. No. 1 is 50.00 Kgs. & Sr. No. 2 is 250.00 Kgs.))	1 Number	1	Clindamycin Phosphate USP	525.00 mg / pack
			2	HYDROUS BENZOYL PEROXIDE USP	2625.00 mg / pack
4	Adapalene & Benzoyl Peroxide Gel 0.1percent/2.5percent (Pack Size 45gm Pack) ((Net Wt. of Import Item Sr. No. 2 is 112.50 Kgs.))	1 Number	2	HYDROUS BENZOYL PEROXIDE USP	1181.25 mg / pack

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

Case No.	163 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002649AM23
RA File Number	03AX04002620 AM23
Licence No and Date	0311017259/16/08/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202223/17 dated 13/01/2023** against advance authorization No. **0311007392 dated 01/10/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

(A)

Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	ALLOPURINOL TABLETS 100MG (Each Allopurinol Tablet of 100mg contains Allopurinol 100mg)(Equivalent to:-Cyano Acetamide 0.0001mg,Triethyl Ortho formate 0.00021mg, Formamide 0.00015 mg, Morpholine 0.00013mg, Hydrazine Hydrate	1 Number	1	Allopurinol	102.00 mg / 100 mg Tablet

	0.00006 mg) Net wt of Allopurinol 15000 kgs (Cross Norms of Allopurinol SION No.A2321 & Tablets/Capsules A412))				
2	ALLOPURINOL TABLETS 300MG (Each Allopurinol Tablet of 300mg contains Allopurinol 300 mg)(Equivalent to:-Cyano Acetamide 0.0003mg ,Triethyl Ortho-formate 0.00063mg, Formamide 0.00045 mg, Morpholine 0.00039mg , Hydrazine Hydrate 0.00018 mg) Net wt of Allopurinol 15000 kgs. (Cross Norms of Allopurinol SION No.A2321 & Tablets/Capsules A412))	1 Number	2	Allopurinol	306.00 mg / 300 mg Tablet

(B)

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

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

Case No.	164 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SUVEN PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002650AM23

RA File Number	09AX04000426 AM23
Licence No and Date	0911003473/16/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	165 / NC/3/MEET/Jan/202223/18													
Case Status	Case Approved													
Party Name	MICRO LABS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00002651AM23													
RA File Number	07AX04000712 AM23													
Licence No and Date	0711005013/16/08/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. 15/82-ALC4/2018 dated 22/03/2019 against advance authorization No. 0710112960 dated 13/03/2018 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>OLOPATADINE HYDROCHLORIDE OPTHALMIC SOLUTION 0.1% w/v 5ml(Each ml contains 1.11 mg of Olopatadine Hydrochloride) (Net Content 666.00 grams))</td><td>120000 Numbers</td><td>1</td><td>OLOPATADINE HYDROCHLORIDE USP / Ph.Eur.</td><td>679.32 gram</td></tr></table>					Export Product	Qty.	Sl. No.	Import items	Qty.	OLOPATADINE HYDROCHLORIDE OPTHALMIC SOLUTION 0.1% w/v 5ml(Each ml contains 1.11 mg of Olopatadine Hydrochloride) (Net Content 666.00 grams))	120000 Numbers	1	OLOPATADINE HYDROCHLORIDE USP / Ph.Eur.	679.32 gram
Export Product	Qty.	Sl. No.	Import items	Qty.										
OLOPATADINE HYDROCHLORIDE OPTHALMIC SOLUTION 0.1% w/v 5ml(Each ml contains 1.11 mg of Olopatadine Hydrochloride) (Net Content 666.00 grams))	120000 Numbers	1	OLOPATADINE HYDROCHLORIDE USP / Ph.Eur.	679.32 gram										
RA concerned may take further necessary action as per above decision of NC														

Case No.	166 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002652AM23
RA File Number	07AX04000627 AM23
Licence No and Date	0711005017/16/08/2022
Norms Committee Decision:	

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

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty.
1	LISINOPRIL 2.5 MG TABLETS(BP/EP/IP/USP 7.50 Kg)	1 Number	1	Lisinopril Dihydrate Ph. Eur.	2.55 mg / Tablet
2	LISINOPRIL 5 MG TABLETS(BP/EP/IP/USP 15.00 Kg)	1 Number	2	Lisinopril Dihydrate Ph. Eur.	5.10 mg / Tablet
3	LISINOPRIL 10 MG TABLETS(BP/EP/IP/USP 90.00 Kg)	1 Number	3	Lisinopril Dihydrate Ph. Eur.	10.20 mg / Tablet
4	LISINOPRIL 20 MG TABLETS(BP/EP/IP/USP 180.00 Kg)	1 Number	4	Lisinopril Dihydrate Ph. Eur.	20.40 mg / Tablet

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

Case No.	167 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002662AM23
RA File Number	07AX04000714 AM23
Licence No and Date	0711005023/17/08/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import items	Qty.
Azelastine Hydrochloride Eye Drops, Solution 0.5% w/v (Azelastine	38000 Numbers	1	AZELASTINE HYDROCHLORIDE Ph. Eur.	193.8 gram

Hydrochloride 0.5mg / ml Eye Drops, Solution) 10ml({ Net Content 190.00 gm})				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	168 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	KLJ PLASTICIZERS LIMITED.
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002668AM23
RA File Number	05AX04001382 AM23
Licence No and Date	0511014320/17/08/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Molecular weight of import and export item. ii. Stoichiometric balance on the basis of molecular weight and yield. iii. Percentage purity of Export Product.	

Case No.	169 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002678AM23
RA File Number	31AX04000141 AM23
Licence No and Date	3111001623/17/08/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No. 3111001358 dated 17/05/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Export product	Qty.	Sl. No.	Import items	Qty.
DNOVO BP818 (Powder) (Tetra Methyl Bisphenol F)	1 kg	1	OCP 50 (O-Cresol and Phenol)	0.23136 kg
		2	Paraformaldehyde	0.14090 kg
		3	Methanol	Not allowed
		4	Katalco 71 5	0.004 kg

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

Case No.	170 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002680AM23
RA File Number	05AX04001361 AM23
Licence No and Date	0511014334/17/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	171 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ASMEE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002687AM23
RA File Number	03AX04002781 AM23
Licence No and Date	0311017314/18/08/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Complete chemical reactions with molecular and structural formula and molecular weights along with	

stage wise percentage yields on molar basis.
ii. Production / Consumption data duly certified by GST.

Case No.	172 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002693AM23
RA File Number	07AX04000739 AM23
Licence No and Date	0711005063/19/08/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. DML. ii. Master Batch Formula.	

Case No.	173 / NC/3/MEET/Jan/202223/18													
Case Status	Case Approved													
Party Name	YASHO INDUSTRIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00002695AM23													
RA File Number	03AX04002817 AM23													
Licence No and Date	0311017348/21/08/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No 6/82-ALC4/2018 dated 26/07/2018 against advance authorization No. 0310814211 dated 22/06/2017 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="2">DI-OCTYLATED DIPHENYLAMINE (YALUB DODPA)</td><td rowspan="2">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></table>		Export product	Qty.	Sl. No.	Import items	Qty.	DI-OCTYLATED DIPHENYLAMINE (YALUB DODPA)	1 kg	1	DIPHENYLAMINE	0.50 kg	2	DI-ISOBUTYLENE	0.64 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
DI-OCTYLATED DIPHENYLAMINE (YALUB DODPA)	1 kg	1	DIPHENYLAMINE	0.50 kg										
		2	DI-ISOBUTYLENE	0.64 kg										

		3	ACTIVATED CLAY	0.10 kg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	174 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002696AM23
RA File Number	03AX04002836 AM23
Licence No and Date	0311017351/22/08/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/14 dated 07/12/2022** against advance authorization No. **0311010308 dated 10/01/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty.
1	Atorvastatin Calcium Tablets USP 10mg((Net wt. of Import Sr. No. 1 is 495.945kgs, Sr. No. 2 is 2746.71kg, Sr. No. 3 is 779.985kg, Sr. No. 4 is 505000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	11.415 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	64.578 mg
			3	Calcium Acetate	18.049 mg
			4	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant as per packing policy
2	Atorvastatin Calcium Tablets USP 20mg((Net wt. of Import Sr. No. 1 is 59.513kgs, Sr. No. 2 is 330.772kg, Sr. No. 3 is 93.879kg, Sr. No. 4 is 30300 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427 mg
			3	Calcium Acetate	36.090 mg

			4	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant as per packing policy
3	Atorvastatin Calcium Tablets USP 40mg((Net wt. of Import Sr. No. 1 is 3570.804kgs, Sr. No. 2 is 19777.77kg, Sr. No. 3 is 5616.216kg, Sr. No. 4 is 909000 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	258.08 mg
			3	Calcium Acetate	71.963 mg
			4	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant as per packing policy
4	Atorvastatin Calcium Tablets USP 80mg((Net wt. of Import Sr. No. 1 is 2063.131kgs, Sr. No. 2 is 11482.123kg, Sr. No. 3 is 3258.146kg, Sr. No. 4 is 262600 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	91.20 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	518.206 mg
			3	Calcium Acetate	144.929 mg
			4	Silica Gel Dessicants - Packaged Activated Carbon (Strippax Sorbent)	Relevant as per packing policy
Note: The above norms are valid only for subject to fulfillment of following conditions: 1. Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application) of Apotex Corp, US. Agent for Apotex Inc., Candada. 2. Export to USA only. 3. Firm holding Certificate of Manufacturing Exclusivity.					
RA concerned may take further necessary action as per above decision of NC.					

Case No.	175 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002697AM23
RA File Number	08AX04000846 AM23

Licence No and Date	0811005777/22/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	176 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	GLENMARK PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM APPLY 00002706AM23			
RA File Number	03AX04002788 AM23			
Licence No and Date	0311017379/22/08/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No. 0311013460 dated 30/03/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

Case No.	177 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002714AM23
RA File Number	09AX04000432 AM23
Licence No and Date	0911003510/22/08/2022
Norms Committee Decision:	

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

Export product	Qty.	Sl. No.	Import items	Qty.
Valganciclovir Tablets USP 450 mg	1 Number	1	Valganciclovir Hcl (USP Amorphous)	506.24 mg

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

Case No.	178 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002737AM23
RA File Number	07AX04000747 AM23
Licence No and Date	0711005078/23/08/2022

Norms Committee Decision:

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

- i. **DML.**
- ii. **Master Batch Formula.**

Case No.	179 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002742AM23
RA File Number	34AX04000462 AM23
Licence No and Date	3411002662/23/08/2022

Norms Committee Decision:

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

- i. **DML.**
- ii. **Master Batch Formula.**

Case No.	180 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002755AM23
RA File Number	34AX04000497 AM23
Licence No and Date	3411002675/24/08/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Step wise manufacturing process. ii. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. iii. Complete technical details as per Annexure to Appendix 4E for chemical products. iv. Stoichiometric balance between import and export on molar basis. v. Details of indigenous input with quantity. vi. Production / Consumption data for last two years duly certified by GST.	

Case No.	181 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002758AM23
RA File Number	08AX04000605 AM23
Licence No and Date	0811005824/24/08/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	182 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023

HQ File Number	HQRNORM APPLY 00002763AM23			
RA File Number	09AX04000349 AM23			
Licence No and Date	0911003525/24/08/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jul/202122/4 dated 15/07/2021 against advance authorization No. 0911000447 dated 26/02/2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Daptomycin for Injection 500mg/vial	400000	1	Daptomycin	220.00 kg
	Numbers			
RA concerned may take further necessary action as per above decision of NC.				

Case No.	183 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	EUGIA PHARMA SPECIALITIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002764AM23
RA File Number	09AX04000315 AM23
Licence No and Date	0911003526/24/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	184 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	WEST BENGAL CHEMICAL INDUSTRIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002765AM23
RA File Number	02AX04000280 AM23
Licence No and Date	0211002902/24/08/2022
Norms Committee Decision:	

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

- i. **Step wise manufacturing process.**
- ii. **Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.**
- iii. **Complete technical details as per Annexure to Appendix 4E for chemical products.**
- iv. **Stoichiometric balance between import and export on molar basis.**
- v. **Details of indigenous input with quantity.**

Case No.	185 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002772AM23
RA File Number	03AX04002827 AM23
Licence No and Date	0311017461/25/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	186 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002776AM23
RA File Number	03AX04002881 AM23
Licence No and Date	0311017468/25/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	187 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	KREATIVE ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002807AM23
RA File Number	09AX04000474 AM23
Licence No and	0911003550/26/08/2022

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
ETODOLAC METHYL ESTER	1 kg	1	2-ETHYL ANILINE / 2-ETHYL BENZENEAMINE	1.058 kg
		2	2,3-DIHYDROFURANE	0.330 kg
		3	METHYL 3 OXO PENTONOATE	0.455 kg
		4	Methanol	1.133 kg
		5	Toluene	Not shown in the process
		6	Sodium Nitrite	0.40 kg
		7	Sodium Sulfite	2.20 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	188 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002809AM23
RA File Number	34AX04000499 AM23
Licence No and Date	3411002686/26/08/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No. 3411002081 dated 31/03/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details	

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

Export product	Qty.	Sl. No.	Import items	Qty.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	189 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002810AM23
RA File Number	34AX04000500 AM23
Licence No and Date	3411002689/26/08/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **3411002081 dated 31/03/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	190 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002813AM23
RA File Number	07AX04000768 AM23

Licence No and Date	0711005110/26/08/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Specify the grade of Citric Acid and Magnesium Carbonate. ii. Manufacturing process indicating the grade of chemicals to use. iii. Use of Potassium Carbonate Granular. iv. Reason for using Granular form of Potassium Carbonate.	

Case No.	191 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002801AM23
RA File Number	09AX04000470 AM23
Licence No and Date	0911003541/26/08/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	192 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM APPLY 00002826AM23			
RA File Number	03AX04002925 AM23			
Licence No and Date	0311017549/29/08/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Dec/202223/15 dated 29/12/2022 against advance authorization No. 0311016722 dated 29/07/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

AMANTADINE HYDRCHLORIDE 100MG CAPSULES	1 Number	1	AMANTADINE HYDROCHLORIDE	102 mg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	193 / NC/3/MEET/Jan/202223/18													
Case Status	Case Approved													
Party Name	JUBILANT INGREVIA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00002835AM23													
RA File Number	05AX04001515 AM23													
Licence No and Date	0511014526/29/08/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="2">Choline Chloride 60% Aqueous</td><td rowspan="2">1 kg</td><td>1</td><td>Ethylene Oxide</td><td>0.197 kg</td></tr><tr><td>2</td><td>Trimethyl Amine</td><td>0.261 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Choline Chloride 60% Aqueous	1 kg	1	Ethylene Oxide	0.197 kg	2	Trimethyl Amine	0.261 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Choline Chloride 60% Aqueous	1 kg	1	Ethylene Oxide	0.197 kg										
		2	Trimethyl Amine	0.261 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	194 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002838AM23
RA File Number	34AX04000490 AM23
Licence No and Date	3411002712/29/08/2022
Norms Committee Decision:	

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

- i. **DML.**
- ii. **Master Batch Formula.**

Case No.	195 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	GODAVARI BIOREFINERIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002842AM23
RA File Number	03AX04002739 AM23
Licence No and Date	0311017558/29/08/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	196 / NC/3/MEET/Jan/202223/18													
Case Status	Case Approved													
Party Name	YASHO INDUSTRIES LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00002846AM23													
RA File Number	03AX04002941 AM23													
Licence No and Date	0311017563/30/08/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No 5/82-ALC4/2018 dated 25/07/2018 against advance authorization No. 0310811041 dated 08/02/2017 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="2">BUTYLATED OCTYLATED DIPHENYLAMINE (YALUB BODPA)</td><td rowspan="2">1 kg</td><td>1</td><td>DIPHENYLAMINE</td><td>0.405 kg</td></tr><tr><td>2</td><td>DIISOBUTYLENE</td><td>0.62 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	BUTYLATED OCTYLATED DIPHENYLAMINE (YALUB BODPA)	1 kg	1	DIPHENYLAMINE	0.405 kg	2	DIISOBUTYLENE	0.62 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
BUTYLATED OCTYLATED DIPHENYLAMINE (YALUB BODPA)	1 kg	1	DIPHENYLAMINE	0.405 kg										
		2	DIISOBUTYLENE	0.62 kg										

		3	ACTIVATED CLAY	0.20 kg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	197 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002854AM23
RA File Number	09AX04000430 AM23
Licence No and Date	0911003559/30/08/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the details furnished by the firm are misleading as they have applied for import of raw material and the intermediate manufactured from these raw material. In view of above, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	198 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002857AM23
RA File Number	09AX04000483 AM23
Licence No and Date	0911003562/30/08/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	199 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002871AM23
RA File Number	08AX04000919 AM23

Licence No and Date	0811005862/01/09/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. DML. ii. Master Batch Formula. iii. COA of import item showing Actual Potency.	

Case No.	200 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	AMI ORGANICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM APPLY 00002873AM23			
RA File Number	52AX04001623 AM23			
Licence No and Date	5211003147/01/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No 13/AM19 dated 14/01/2019 against advance authorization No. 5210041615 dated 21.08.2015 and 5210042176 dated 10.02.2017, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

Case No.	201 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	HI-PURITY CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002877AM23
RA File Number	03AX04002948 AM23
Licence No and Date	0311017592/01/09/2022
Norms Committee Decision: The Committee considered the case as per agenda 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.	

Case No.	202 / NC/3/MEET/Jan/202223/18													
Case Status	Case Approved													
Party Name	BIODEAL PHARMACEUTICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00002909AM23													
RA File Number	05AX04001425 AM23													
Licence No and Date	0511014609/02/09/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Aug/202223/6 dated 09/09/2022 against advance authorization No. 0511008526 dated 03/02/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="2">NASAL SPRAY(SNAP-ON, S20 WHITE SMOOTH, NASAL ADAPTOR AT PAG136, AM TL 17 ML, 14-0388-004, WHITE, BOTTLE WITH CHEMICALS AS PER THE DRUG LICENSE)</td><td rowspan="2">99000 Numbers</td><td>1</td><td>NASAL ADAPTOR FOR MFG OF NASAL SPRAY</td><td>Relevant, on Net to Net basis with accountability</td></tr><tr><td>2</td><td>NASAL BOTTLE</td><td>Relevant, on Net to Net basis with accountability</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	NASAL SPRAY(SNAP-ON, S20 WHITE SMOOTH, NASAL ADAPTOR AT PAG136, AM TL 17 ML, 14-0388-004, WHITE, BOTTLE WITH CHEMICALS AS PER THE DRUG LICENSE)	99000 Numbers	1	NASAL ADAPTOR FOR MFG OF NASAL SPRAY	Relevant, on Net to Net basis with accountability	2	NASAL BOTTLE	Relevant, on Net to Net basis with accountability
Export product	Qty.	Sl. No.	Import items	Qty.										
NASAL SPRAY(SNAP-ON, S20 WHITE SMOOTH, NASAL ADAPTOR AT PAG136, AM TL 17 ML, 14-0388-004, WHITE, BOTTLE WITH CHEMICALS AS PER THE DRUG LICENSE)	99000 Numbers	1	NASAL ADAPTOR FOR MFG OF NASAL SPRAY	Relevant, on Net to Net basis with accountability										
		2	NASAL BOTTLE	Relevant, on Net to Net basis with accountability										

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

Case No.	203 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002916AM23
RA File Number	31AX04000160 AM23
Licence No and Date	3111001669/02/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/14 dated 07/12/2022** against advance authorization No. **3111000158 dated 08/03/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
MORPHOLINE (ORGANIC CHEMICAL)	1 kg	1	DIETHYLENE GLYCOL	1.279 kg
		2	AMMONIA ANHYDROUS	0.217 kg
		3	HYDROGEN	Not allowed, as it is procured indigenously.
		4	MORPHOLINE CATALYST	Not allowed as no catalogue is available.

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

Case No.	204 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DIAMINES AND CHEMICALS LIMITED
Meeting Number	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023

and Date	
HQ File Number	HQRNORM APPLY 00002917AM23
RA File Number	34AX04000464 AM23
Licence No and Date	3411002727/02/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information:	
i. COA report of both import and export items giving clearly percentage of it purity. ii. Production of export item vis-à-vis Consumption of all the raw materials (both imported and indigenous) for last three years duly certified by GST / CA. iii. Total sales value of By-Product per kg of export item, giving evidence and also to subtract the quantity of import item per kg of export from this value.	

Case No.	205 / NC/3/MEET/Jan/202223/18				
Case Status	Case Approved				
Party Name	ALEMBIC PHARMACEUTICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023				
HQ File Number	HQRNORM APPLY 00002918AM23				
RA File Number	34AX04000542 AM23				
Licence No and Date	3411002728/02/09/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Nov/202223/14 dated 07/12/2022 against advance authorization No. 3411001604 dated 29/12/2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					

				grade)	
			5	Sucrose (Compressuc PS)	15.67 mg
			6	Hypromellose Phthalate (HP 55)	12.07 mg
			7	Triethyl Citrate	1.21 mg
2	Duloxetine Caps. 30 mg (Duloxetine Caps. 30 mg (Net content of active ingredients 210.00 kgs))	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	34.36 mg
			2	Sugar Spheres (30-35 PHARM-A-SPHERES)	30.50 mg
			3	Hypromellose (Pharmacoat 606)	30.00 mg
			4	Talc (Luzenac Pharma Ultra Micronised grade)	18.94 mg
			5	Sucrose (Compressuc PS)	23.50 mg
			6	Hypromellose Phthalate (HP 55)	18.10 mg
			7	Triethyl Citrate	1.81 mg
3	Duloxetine Caps. 40 mg (Duloxetine Caps. 40 mg (Net content of active ingredients 120.000 kgs))	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	45.76 mg
			2	Sugar Spheres (30-35 PHARM-A-SPHERES)	40.67 mg
			3	Hypromellose (Pharmacoat 606)	40.00 mg
			4	Talc (Luzenac Pharma Ultra Micronised grade)	25.26 mg
			5	Sucrose (Compressuc PS)	31.34 mg
			6	Hypromellose Phthalate (HP 55)	24.14 mg
			7	Triethyl Citrate	2.41 mg

4	Duloxetine Caps. 60 mg (Duloxetine Caps. 60 mg (Net content of active ingredients 450.00 kgs))	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	68.71 mg
			2	Sugar Spheres (30-35 PHARM-A-SPHERES)	61.00 mg
			3	Hypromellose (Pharmacoat 606)	60.00 mg
			4	Talc (Luzenac Pharma Ultra Micronised grade)	37.88 mg
			5	Sucrose (Compressuc PS)	47.00 mg
			6	Hypromellose Phthalate (HP 55)	36.20 mg
			7	Triethyl Citrate	3.62 mg

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

Case No.	206 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002919AM23
RA File Number	34AX04000543 AM23
Licence No and Date	3411002729/02/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	207 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002922AM23
RA File Number	07AX04000800 AM23
Licence No and Date	0711005150/02/09/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0711003587 dated 03/04/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
10mL Vial - filled with 90mg of Sodium Chloride as bulk drug filled in 10mL Vial and capped with 13mm GreySerum Chlorobu(10mL Vial - filled with 90mg of Sodium Chloride as bulk drug filled in 10mL Vial and capped with 13mm GreySerum ChlorobutyI Rubber Stopper)	1038636 Numbers	1	13mm Grey Serum ChlorobutyI R/S-RFS-C14226422GS6TP3	Relevant as per Packing Policy

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

Case No.	208 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002907AM23
RA File Number	08AX04000900 AM23
Licence No and Date	0811005875/02/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202122/12 dated 17/12/2021** against advance authorization No. **0711001531 dated 22/07/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	BISOPROLOL FUMARATE 5MG TABLETS (Bisprol 5mg, Bisolen 5mg)(Each film coated tablet contains Bisprolol Fumarate Ph. Eur 5 mg and Excipients. Net content of Bisoprolol Fumarate should not be less than 65 Kg in export item.)	1 Number	1	BISPROLOL FUMARATE	5.10 mg / 5 mg Tablet

2	BISOPROLOL FUMARATE 10MG TABLETS (Biprol 10mg)(Each film coated tablet contains Bisoprolol Fumarate Ph. Eur 10 mg and Excipients. Net content of Bisoprolol Fumarate should not be less than 68 Kg in export item.)	1 Number	1	BISOPROLOL FUMARATE	10.20 mg / 10 mg Tablet
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RA concerned may take further necessary action as per above decision of NC.

Case No.	209 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002908AM23
RA File Number	09AX04000467 AM23
Licence No and Date	0911003577/02/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jan/202122/13 dated 21/01/2022** against advance authorization No. **0911001571 dated 17/09/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Aztreonam for Injection USP 1 Gram ((Contains a blend of Sterile Aztreonam 56 percent and Arginine 44 percent))	1 Number	1	Aztreonam and Arginine (56:44)	1.10 gram / vial
2	Aztreonam for Injection USP 500 mg ((Contains a blend of Sterile Aztreonam 56 percent and Arginine 44 percent))	1 Number	2	Aztreonam and Arginine (56:44)	0.55 gram / vial

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

Case No.	210 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved

Party Name	GLENMARK PHARMACEUTICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023				
HQ File Number	HQRNORM APPLY 00002936AM23				
RA File Number	03AX04002732 AM23				
Licence No and Date	0311017630/03/09/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jan/202021/4 dated 12/02/2021 against advance authorization No. 0310835970 dated 26/04/2020, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export Product	Qty	Sl. No.	Import Items	Qty
1	Ciclopirox Gel 0.77percent (Pack 30 Gms) (Net wt. of Ciclopirox USP is 20.790 Kgs.)	1 Number	1	Ciclopirox USP	235.62 mg / pack
2	Ciclopirox Gel 0.77percent (Pack 45 Gms) (Net wt. of Ciclopirox USP is 17.325 Kgs.)	1 Number	1	Ciclopirox USP	352.967 mg / pack
3	Ciclopirox Gel 0.77percent (Pack 100 Gms) (Net wt. of Ciclopirox USP is 50.05 Kgs.)	1 Number	1	Ciclopirox USP	785.00 mg / pack
RA concerned may take further necessary action as per above decision of NC.					

Case No.	211 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002945AM23
RA File Number	03AX04002741 AM23
Licence No and Date	0311017118/05/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product /	

import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0311013625 dated 05/04/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
CILOSTAZOL	1 kg	1	5-(4-CHLOROBUTYL)-1-CYCLOHEXYL 1H TETRAZOLE	0.85 kg
		2	6-HYDROXY-2 OXO-1,2,3,4-TETRAHYDROQUINOLINE	0.59 kg
		3	METHANOL	4.00 kg
		4	TOLUENE	0.30 kg
		5	TRICAPRLY METHYL AMMONIUM CHLORIDE	0.100 kg

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

Case No.	212 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002944AM23
RA File Number	07AX04000812 AM23
Licence No and Date	0711005159/05/09/2022

Norms Committee Decision:

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

- i. Manufacturing process indicating the grade of chemicals to use.**
- ii. Use of Potassium Carbonate Granular.**
- iii. Reason for using Granular form of Potassium Carbonate.**

Case No.	213 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	ENALTEC LABS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00002955AM23													
RA File Number	03AX04002862 AM23													
Licence No and Date	0311017663/06/09/2022													
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. 7/82-ALC4/2020 dated 04/12/2020 against advance authorization No. 0310837576 dated 10/08/2020, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>Febuxostat</td> <td>1 kg</td> <td>1</td> <td>2-[3-Cyano-4-(2-Methylpropoxy) Phenyl]-4-Methyl-5-Thiazolecarboxylic Acid Ethyl Ester</td> <td>1.25 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.	Febuxostat	1 kg	1	2-[3-Cyano-4-(2-Methylpropoxy) Phenyl]-4-Methyl-5-Thiazolecarboxylic Acid Ethyl Ester	1.25 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Febuxostat	1 kg	1	2-[3-Cyano-4-(2-Methylpropoxy) Phenyl]-4-Methyl-5-Thiazolecarboxylic Acid Ethyl Ester	1.25 kg										

Case No.	214 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00002981AM23
RA File Number	05AX04001405 AM23
Licence No and Date	0511014704/07/09/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: (i) Copy of DML for export item showing Approved Composition. (ii) COA of the export item. (iii) Process details with wastage claimed.	

Case No.	215 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved

Party Name	SENTISS PHARMA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00002983AM23													
RA File Number	05AX04001633 AM23													
Licence No and Date	0511014706/07/09/2022													
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No. 0511011311 dated 23/03/2022, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>Inokain Eye Drops 0.4% 5ml</td> <td>1 Vial</td> <td>1</td> <td>Benoxinate HCL</td> <td>20.4 mg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export product	Qty.	Sl. No.	Import items	Qty.	Inokain Eye Drops 0.4% 5ml	1 Vial	1	Benoxinate HCL	20.4 mg
Export product	Qty.	Sl. No.	Import items	Qty.										
Inokain Eye Drops 0.4% 5ml	1 Vial	1	Benoxinate HCL	20.4 mg										

Case No.	216 / NC/3/MEET/Jan/202223/18													
Case Status	Case Approved													
Party Name	MACLEODS PHARMACEUTICALS LTD													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00003019AM23													
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 taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Nov/202223/14 dated 07/12/2022 against advance authorization No. 0311001091 dated 20/01/2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>Lamivudine 300mg + Tenofovir disoproxil</td> <td>1 kg</td> <td>1</td> <td>(R)-3-AMINO-1-BUTANOL</td> <td>19.635 mg</td> </tr> </tbody> </table>					Export product	Qty.	Sl. No.	Import items	Qty.	Lamivudine 300mg + Tenofovir disoproxil	1 kg	1	(R)-3-AMINO-1-BUTANOL	19.635 mg
Export product	Qty.	Sl. No.	Import items	Qty.										
Lamivudine 300mg + Tenofovir disoproxil	1 kg	1	(R)-3-AMINO-1-BUTANOL	19.635 mg										

Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 3443.382 kgs Dolutegravir Sodium + 20660.292 kgs Tenofovir Disoproxil Fumarate + 20660.292 kgs Lamivudine))	2	1-(2,2-dimethoxyethyl)-5-methoxy-6(methoxycarbonyl) 4-oxo-1,4-dihydropyridine-3-carboxylic acid	Indigenously procured
	3	Lithium bromide anhydrous	Indigenously procured
	4	(R)-9-(2-phosphonomethoxy propyl)-adenine	205.02 mg
	5	LAMIVUDINE	Indigenously procured
RA concerned may take further necessary action as per above decision of NC.			

Case No.	217 / NC/3/MEET/Jan/202223/18													
Case Status	Case Approved													
Party Name	UPL LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00002994AM23													
RA File Number	03AX04003042 AM23													
Licence No and Date	0311017718/08/09/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. 6/82-ALC4/2020 dated 13/11/2020 against advance authorization No. 0310831562 dated 16/09/2019 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="2">Triphenyl Phosphite</td><td rowspan="2">1 kg</td><td>1</td><td>Phenol</td><td>0.937 kg</td></tr><tr><td>2</td><td>Yellow Phosphorus</td><td>0.10 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Triphenyl Phosphite	1 kg	1	Phenol	0.937 kg	2	Yellow Phosphorus	0.10 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Triphenyl Phosphite	1 kg	1	Phenol	0.937 kg										
		2	Yellow Phosphorus	0.10 kg										

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

Case No.	218 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003003AM23
RA File Number	03AX04002647 AM23
Licence No and Date	0311017727/08/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	219 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	RINI LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003016AM23
RA File Number	56AX04000128 AM23
Licence No and Date	5611001155/08/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **13/82-ALC4/2018 dated 14/01/2019** against advance authorization No. **5210042754 dated 04/09/2018**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Diacerein / Diacerein In-House / Diacerein INH / Diacerein IP / Diacerein BP / Diacerein EP / Diacerein BP-EP	1 kg	1	ALOE EMODIN 95%	1.05 kg

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

Case No.	220 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred

Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003018AM23
RA File Number	09AX04000445 AM23
Licence No and Date	0911003612/08/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	221 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003021AM23
RA File Number	34AX04000522 AM23
Licence No and Date	3411002756/09/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	222 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	DEEPAK PHENOLICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM APPLY 00003022AM23			
RA File Number	34AX04000564 AM23			
Licence No and Date	3411002761/09/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No. 3411002081 dated 31/03/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	223 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003023AM23
RA File Number	34AX04000550 AM23
Licence No and Date	3411002762/09/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **3411002081 dated 31/03/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	224 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003024AM23
RA File Number	34AX04000559 AM23
Licence No and Date	3411002763/09/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **3411002081 dated 31/03/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Phenol	1 MT	1	Cumene	0.84466 MT

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

Case No.	225 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003029AM23
RA File Number	08AX04000798 AM23
Licence No and Date	0811005961/09/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	226 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003031AM23
RA File Number	08AX04000738 AM23
Licence No and Date	0811005966/09/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	227 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003036AM23
RA File Number	05AX04001577 AM23
Licence No and	0511014727/09/09/2022

Date	
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	228 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003047AM23
RA File Number	03AX04002855 AM23
Licence No and Date	0311017779/12/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/9 dated 07/10/2022** against advance authorization No. **0311011779 dated 25/02/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	METFORMIN 500MG TABLETS((Each Metformin 500mg Tablet contains Metformin HCL 500mg) equivalent to:- Dicyandiamide 289.170 mg, DMF 188.700 mg. Total Net wt of Export 87916.500 kgs (Cross SION Norms of Metformin HCL SION No.A290 & Tablets/Capsules SION No A412.))	1 Number	1	DICYANDIAMIDE	289.17 mg
			2	DMF	188.70 mg
2	METFORMIN 850MG TABLETS((Each Metformin 850mg Tablet contains Metformin HCL 850mg) equivalent to:- Dicyandiamide 491.589 mg, DMF 320.790 mg. Total Net wt of Export 15597.925 kgs (Cross SION Norms of Metformin HCL SION No.A290 & Tablets/Capsules SION No A412.))	1 Number	3	DICYANDIAMIDE	491.589 mg
			4	DMF	320.79 mg
3	METFORMIN 1000MG TABLETS((Each Metformin 1000mg Tablet contains Metformin HCL 1000mg) equivalent to:- Dicyandiamide 578.340 mg, DMF 377.400 mg. Total Net wt of Export 103008.000 kgs (Cross SION Norms of Metformin HCL SION No.A290 & Tablets/Capsules SION No A412.))	1 Number	5	DICYANDIAMIDE	578.34 mg
			6	DMF	377.40 mg

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

Case No.	229 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003055AM23
RA File Number	03AX04002864 AM23
Licence No and Date	0311017789/12/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202223/17 dated 13/01/2023** against advance authorization No. **0311007392 dated 01/10/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

(A)

Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	ALLOPURINOL TABLETS 100MG (Each Allopurinol Tablet of 100mg contains Allopurinol 100mg)(Equivalent to:-Cyano Acetamide 0.0001mg,Triethyl Ortho-formate 0.00021mg, Formamide 0.00015 mg, Morpholine 0.00013mg, Hydrazine Hydrate 0.00006 mg) Net wt of Allopurinol 25000 kgs (Cross Norms Allopurinol SION No.A2321 & Tablets/Capsules A412.))	1 Number	1	Allopurinol	102.00 mg / 100 mg Tablet
2	ALLOPURINOL TABLETS 300MG (Each Allopurinol Tablet of 300mg contains Allopurinol 300 mg)(Equivalent to:- Cyano Acetamide 0.0003mg,Triethyl Ortho-formate 0.00063mg, Formamide 0.00045 mg, Morpholine 0.00039mg, Hydrazine Hydrate 0.00018 mg) Net wt of Allopurinol 25000 kgs. (Cross Norms of Allopurinol SION No.A2321 & Tablets/Capsules A412.))	1 Number	2	Allopurinol	306.00 mg / 300 mg Tablet

(B)

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

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

Case No.	230 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTIGREAT CONSULTING SERVICES LLP
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003056AM23
RA File Number	03AX04002543 AM23
Licence No and Date	0311017790/12/09/2022

Norms Committee Decision:

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

- i. **DML.**
- ii. **Master Batch Formula.**
- iii. **Complete description of import item alongwith its COA.**

Case No.	231 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003057AM23
RA File Number	03AX04002669 AM23
Licence No and Date	0311017791/12/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	232 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003058AM23
RA File Number	30AX04000258 AM23
Licence No and Date	3011002579/12/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	233 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003064AM23
RA File Number	05AX04001671 AM23
Licence No and Date	0511014757/12/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity.	

Case No.	234 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SOHAN HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003065AM23
RA File Number	31AX04000173 AM23
Licence No and Date	3111001690/12/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	235 / NC/3/MEET/Jan/202223/18										
Case Status	Case Approved										
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023										
HQ File Number	HQRNORM APPLY 00003068AM23										
RA File Number	05AX04001554 AM23										
Licence No and Date	0511014763/12/09/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Mar/202122/16 dated 08/04/2022 against advance authorization No. 0511005404 dated 13/10/2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Brinzolamide Ophthalmic Suspension, 1% w/v 5ml (Sterile Eye Drops) (BRINOLAR / BRAZTEC)((Each ml contains Brinzolamide equivalent to Brinzolamide Micronized Sterile 10 mg (Equivalent to 1150 Gm of Bulk Drug),)</td><td>23000 Numbers</td><td>1</td><td>Brinzolamide Micronized Sterile</td><td>1173 gram</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Brinzolamide Ophthalmic Suspension, 1% w/v 5ml (Sterile Eye Drops) (BRINOLAR / BRAZTEC)((Each ml contains Brinzolamide equivalent to Brinzolamide Micronized Sterile 10 mg (Equivalent to 1150 Gm of Bulk Drug),)	23000 Numbers	1	Brinzolamide Micronized Sterile	1173 gram
Export product	Qty.	Sl. No.	Import items	Qty.							
Brinzolamide Ophthalmic Suspension, 1% w/v 5ml (Sterile Eye Drops) (BRINOLAR / BRAZTEC)((Each ml contains Brinzolamide equivalent to Brinzolamide Micronized Sterile 10 mg (Equivalent to 1150 Gm of Bulk Drug),)	23000 Numbers	1	Brinzolamide Micronized Sterile	1173 gram							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	236 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved

Party Name	VISION DRUGS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM APPLY 00003087AM23			
RA File Number	09AX04000495 AM23			
Licence No and Date	0911003620/13/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Nov/202223/14 dated 07/12/2022 against advance authorization No. 0911002377 dated 27/01/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

Case No.	237 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SUDEEP NUTRITION PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003092AM23
RA File Number	34AX04000422 AM23
Licence No and Date	3411002775/13/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	238 / NC/3/MEET/Jan/202223/18			
Case Status	Case Deferred			
Party Name	AURORE LIFE SCIENCES PRIVATE LIMITED			
Meeting Number	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			

and Date	
HQ File Number	HQRNORM APPLY 00003118AM23
RA File Number	09AX04000498 AM23
Licence No and Date	0911003623/14/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	239 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003140AM23
RA File Number	08AX04001000 AM23
Licence No and Date	0811006039/15/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	240 / NC/3/MEET/Jan/202223/18										
Case Status	Case Approved										
Party Name	DEEPAK PHENOLICS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023										
HQ File Number	HQRNORM APPLY 00003150AM23										
RA File Number	34AX04000580 AM23										
Licence No and Date	3411002785/15/09/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No. 3411002081 dated 31/03/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Phenol</td><td>1 MT</td><td>1</td><td>Cumene</td><td>0.84466 MT</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Phenol	1 MT	1	Cumene	0.84466 MT
Export product	Qty.	Sl. No.	Import items	Qty.							
Phenol	1 MT	1	Cumene	0.84466 MT							

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

Case No.	241 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	MEGHMANI NOVOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003128AM23
RA File Number	08AX04000233 AM23
Licence No and Date	0811006022/15/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	242 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003129AM23
RA File Number	08AX04000980 AM23
Licence No and Date	0811006023/15/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	243 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003131AM23
RA File Number	09AX04000510 AM23
Licence No and Date	0911003627/15/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No. 0911002994 dated 13/05/2022, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Export product	Qty.	Sl. No.	Import items	Qty.
LINEZOLID	1 kg	1	3,4-Difluoro Nitrobenzene	0.80 kg
		2	(S)-(+)-Epichlorohydrin (OR) (s)-(+)-2-(Chloromethyl) Oxirane	0.80 kg
		3	Triethyl Amine	0.20 kg
		4	Ethyl Acetate	2.50 kg
		5	Isopropyl Alcohol (IPA)	2.00 kg
		6	Hydrazine Hydrate	1.00 kg
		7	Methylene Di Chloride (MDC)	0.80 kg
		8	Methanol	1.50 kg

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

Case No.	244 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003134AM23
RA File Number	03AX04002730 AM23
Licence No and Date	0311017884/15/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	245 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	KRITI NUTRIENTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003136AM23

RA File Number	56AX04000172 AM23
Licence No and Date	5611001168/15/09/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case alongwith following documents / information: (i) Complete specification and COA of import item from foreign supplier. (ii) Point out the difference in specification of import and export. (iii) Production / Consumption data for last two years duly certified by GST.	

Case No.	246 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003172AM23
RA File Number	03AX04003088 AM23
Licence No and Date	0311017943/16/09/2022
Norms Committee Decision: Deferred for comments of TE	

Case No.	247 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	DEEPAK PHENOLICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM APPLY 00003155AM23			
RA File Number	34AX04000585 AM23			
Licence No and Date	3411002788/16/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No. 3411002081 dated 31/03/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.

Phenol	1 MT	1	Cumene	0.84466 MT
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RA concerned may take further necessary action as per above decision of NC.

Case No.	248 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003157AM23
RA File Number	05AX04001704 AM23
Licence No and Date	0511014859/16/09/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis. Details of indigenous input with quantity.	

Case No.	249 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003158AM23
RA File Number	05AX04001697 AM23
Licence No and Date	0511014860/16/09/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.	

- iii. Complete technical details as per Annexure to Appendix 4E for chemical products.
- iv. Stoichiometric balance between import and export on molar basis.
- v. Details of indigenous input with quantity.
- vi. End use of Export Product.

Case No.	250 / NC/3/MEET/Jan/202223/18													
Case Status	Case Approved													
Party Name	PRAKASH CHEMICALS INTERNATIONAL PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00003165AM23													
RA File Number	34AX04000572 AM23													
Licence No and Date	3411002790/16/09/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/20222/8 dated 23/09/2022 against advance authorization No. 3411000924 dated 02/08/2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: <table border="1"> <thead> <tr> <th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> <tr> <td rowspan="2">Hexyl Salicylate((n-Hexyl-ortho-Hydroxy Benzoate))</td><td rowspan="2">1 kg</td><td>1</td><td>n-Hexanol (Lorol C 6/ Nacol 6-99)</td><td>0.438 kg</td></tr> <tr> <td>2</td><td>Salicylic Acid</td><td>0.654 kg</td></tr> </tbody> </table>		Export product	Qty.	Sl. No.	Import items	Qty.	Hexyl Salicylate((n-Hexyl-ortho-Hydroxy Benzoate))	1 kg	1	n-Hexanol (Lorol C 6/ Nacol 6-99)	0.438 kg	2	Salicylic Acid	0.654 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Hexyl Salicylate((n-Hexyl-ortho-Hydroxy Benzoate))	1 kg	1	n-Hexanol (Lorol C 6/ Nacol 6-99)	0.438 kg										
		2	Salicylic Acid	0.654 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	251 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	TULIP LAB PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003167AM23
RA File Number	03AX04003046 AM23
Licence No and Date	0311017934/16/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	252 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003169AM23
RA File Number	03AX04003215 AM23
Licence No and Date	0311017939/16/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	253 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003187AM23
RA File Number	08AX04000985 AM23
Licence No and Date	0811006052/19/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	254 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003190AM23
RA File Number	30AX04000248 AM23
Licence No and Date	3011002599/19/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and on the basis of written comments furnished by Department of Biotechnology vide D.O. Letter No. PID-13011(15)/1/2021-PPB-DBT dated 02.01.2023 in other similar case of the firm, it was decided to call for following information / documents from the firm: i. Justification for claiming 20% wastage. ii. Import input, that is, Urokinase in terms of IU/mg. iii. DML (Drug Manufacturing License).	

Case No.	255 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003195AM23
RA File Number	07AX04000870 AM23
Licence No and Date	0711005273/19/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Nov/202223/12 dated 18/11/2022** against advance authorization No. **0711003861 dated 26/04/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export Product	Qty.	Sl. No.	Import items	Qty.
TRANEXAMIC ACID INJECTION SOLUTION 1000MG / 10ML (TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML (188.70 KG))	1 Number	1	TRANEXAMIC ACID USP	1100 mg / 10 ml Vial

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

Case No.	256 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003244AM23
RA File Number	34AX04000595 AM23
Licence No and Date	3411002799/20/09/2022

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 for explaining its case.

Case No.	257 / NC/3/MEET/Jan/202223/18
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Case Status	Case Deferred
Party Name	CANPEX CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003225AM23
RA File Number	31AX04000170 AM23
Licence No and Date	3111001703/20/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	258 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003228AM23
RA File Number	08AX04000781 AM23
Licence No and Date	0811006058/20/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	259 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	LASENOR INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003231AM23
RA File Number	50AX04000046 AM23
Licence No and Date	5011000583/20/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	260 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003235AM23
RA File Number	09AX04000475 AM23
Licence No and	0911003652/20/09/2022

Date					
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jun/202223/5 dated 08/07/2022 against advance authorization No. 0911001444 dated 30/08/2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Ibuclin Express Sachet Pack Size : 6s (Ibuprofen 400 mg Paracetamol BP 325 mg Power for Oral Solution)(Ibuclin Express Sachet Pack Size : 6s (Ibuprofen 400 mg, Paracetamol BP 325 mg Power for Oral Solution) (Each sachet contains: Ibuprofen Sodium Dihydrate 512 mg, Equivalent to Ibuprofen 400 mg ,Paracetamol BP 325 mg))	1 Number	1	Ibuprofen Sodium Dihydrate	517.12 mg
2	Ibuclin Express Sachet Pack Size : 9s (Ibuprofen 400 mg Paracetamol BP 325 mg Power for Oral Solution)(Ibuclin Express Sachet Pack Size : 9s (Ibuprofen 400 mg, Paracetamol BP 325 mg Power for Oral Solution) (Each sachet contains: Ibuprofen Sodium Dihydrate 512 mg, Equivalent to Ibuprofen 400 mg, Paracetamol BP 325 mg))	1 Number	2	Ibuprofen Sodium Dihydrate	517.12 mg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	261 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003250AM23
RA File Number	03AX04003249 AM23
Licence No and Date	0311018034/21/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. 2/AM21 dated 24/07/2020 against advance authorization No. 0310831252 dated	

27/08/2019, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
3-Chloro-2-Hydrazino Pyridine (KC-190)	1 kg	1	3 AMINO PYRIDINE	1.30 kg
		2	HYDROGEN PEROXIDE	0.942 kg
		3	SODIUM NITRATE	0.950 kg
		4	HYDRAZINE HYDRATE 80 TO 100 PERCENT	1.34 kg

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

Case No.	262 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003251AM23
RA File Number	34AX04000590 AM23
Licence No and Date	3411002800/21/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	263 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003252AM23
RA File Number	03AX04002221 AM23
Licence No and Date	0311018044/21/09/2022
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	264 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003266AM23
RA File Number	08AX04001009 AM23
Licence No and Date	0811006072/21/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	265 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	LASENOR INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003295AM23
RA File Number	50AX04000050 AM23
Licence No and Date	5011000587/22/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	266 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	HONOUR LAB LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM APPLY 00003301AM23			
RA File Number	09AX04000376 AM23			
Licence No and Date	0911003678/22/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

Gemifloxacin Mesylate	1 kg	1	Glycine Ethyl-Ester Hydro Chloride	0.967 kg
		2	Di Tert.Butyl Di Carbonate	2.408 kg
		3	Dimethyl formamide	4.30 kg
		4	Methoxyl Amine HCL	0.404 kg
		5	7-chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid	0.700 kg

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

Case No.	267 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	KALPSUTRA CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003302AM23
RA File Number	03AX04003171 AM23
Licence No and Date	0311018082/22/09/2022

Norms Committee Decision:

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

- i. **Step wise manufacturing process.**
- ii. **Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.**
- iii. **Complete technical details as per Annexure to Appendix 4E for chemical products.**
- iv. **Stoichiometric balance between import and export on molar basis.**
- v. **Details of indigenous input with quantity.**

Case No.	268 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003309AM23
RA File Number	08AX04000971 AM23

Licence No and Date	0811006083/22/09/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jun/2022122/2 dated 02/07/2021 against advance authorization No. 0811001621 dated 01/06/2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop (Considering the loss on drying @14.50% of Bulk(Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop (Considering the loss on drying @14.50% of Bulkdrug for 300MG we need to poor 350.88 Mg. So net content of the raw material is :- 90000 Bottles * 5 ML * 350.88 MG = 157.89 Kgs.))	90000 Numbers	1	Metamizole Magnesium	143.654 kg
2	Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop (Considering the loss on drying @14.50% of Bulk(Metamizaole Magnesium 300 mg and Pargeverine Hydrochloride 6mg Oral Drop (Considering the loss on drying @14.50% of Bulkdrug for 300MG we need to poor 350.88 Mg. So net content of the raw material is :- 1150000 Bottles *15 ML* 350.88 MG = 6052.68 KGS))	1150000 Numbers	2	Metamizole Magnesium	5433.742 kg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	269 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003281AM23
RA File Number	03AX04003217 AM23
Licence No and Date	0311018065/22/09/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Oct/202223/11 dated 31/10/2022** against advance authorization No. **0311000935 dated 14/01/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
2-AMINO -2-PHENYLBUTYRIC ACID SODIUM SALT(2-AMINO PHENYLBUTYRIC ACID SODIUM SALT)	1 kg	1	PROPIOPHENONE	0.922 kg
		2	SODIUM CYANIDE (NaCN)	0.337 kg

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

Case No.	270 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003282AM23
RA File Number	03AX04003288 AM23
Licence No and Date	0311018056/22/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	271 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003283AM23
RA File Number	03AX04003060 AM23
Licence No and Date	0311018071/22/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	272 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	KAVALIFE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003326AM23
RA File Number	07AX04000884 AM23
Licence No and Date	0711005312/23/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	273 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003330AM23
RA File Number	05AX04001819 AM23
Licence No and Date	0511014976/23/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	274 / NC/3/MEET/Jan/202223/18			
Case Status	Case Approved			
Party Name	SENTISS PHARMA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023			
HQ File Number	HQRNORM APPLY 00003332AM23			
RA File Number	05AX04001816 AM23			
Licence No and Date	0511014979/23/09/2022			
Norms Committee Decision:				
: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/202223/8 dated 23/09/2022 against advance authorization No. 0511005004 dated 28/09/2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

TOBRISS (TOBRAMYCIN 0.3 PERCENT) EYE DROPS 5 ML VIAL	1 Number Pack	1	Tobramycin Sulphate	19.057 mg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	275 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	AROHEMA INGREDIENTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003314AM23
RA File Number	26AX04000054 AM23
Licence No and Date	2611000716/23/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	276 / NC/3/MEET/Jan/202223/18
Case Status	Case Rejected
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003318AM23
RA File Number	09AX040000541 AM23
Licence No and Date	0911003683/23/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the details furnished by the firm are misleading as they have applied for import of raw material and the intermediate manufactured from these raw material. In view of above, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	277 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003319AM23

RA File Number	09AX04000545 AM23
Licence No and Date	0911003684/23/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202223/17 dated 13/01/2023** against advance authorization No. **0911002118 dated 21/12/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
sodium (S)-4-oxo-4,6,7,8-tetrahydropyrrolo [1,2-a]pyrimidine-6-carboxylate((Pyrimidinone acid, sodium salt))	1 kg	1	L Pyroglutamic Acid	2.70 kg
		2	Triethyl Amine	2.27 kg
		3	2,5-Norbornadiene	1.73 kg
		4	Chloro Sulfonyl Isocyanate	2.778 kg
		5	Isopropyl Alcohol	4.02 kg
		6	Methyl Tert Butyl Ether	5.91 kg
		7	Toluene	5.72 Litre
		8	Ethyl Acetate	2.95 Litre
		9	N-Heptane	1.82 kg
		10	Ethyl Benzene	1.00 kg
		11	Methanol	1.50 kg
		12	Methylene Chloride	3.25 Litre

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

Case No.	278 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003320AM23
RA File Number	09AX04000492 AM23
Licence No and Date	0911003685/23/09/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee for explaining its case.	

Case No.	279 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003339AM23
RA File Number	03AX04003267 AM23
Licence No and Date	0311018114/24/09/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	280 / NC/3/MEET/Jan/202223/18				
Case Status	Case Approved				
Party Name	MAIVA PHARMA PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023				
HQ File Number	HQRNORM APPLY 00003340AM23				
RA File Number	07AX04000867 AM23				
Licence No and Date	0711005239/24/09/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Dec/202223/15 dated 29/12/2022 against advance authorization No. 0711004485 dated 01/07/2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl.	Export Product	Qty.	Sl. No.	Import items	Qty.

No.					
1	Diltiazem Hydrochloride Injection 5mg/mL, 25mL vial(Diltiazem Hydrochloride Injection 5mg/mL, 25mL vial)	1 Number	1	S-127 4031/45G GRAY SIL WESTAR SELECT RS (20mm Serum Non laminated Bromobutyl R/S RFS)	Relevant as per packing policy
2	Diltiazem Hydrochloride Injection 5mg/mL, 10mL vial(Diltiazem Hydrochloride Injection 5mg/mL, 10mL vial)	1 Number	2	S-127 4031/45G GRAY SIL WESTAR SELECT RS (20mm Serum Non laminated Bromobutyl R/S RFS)	Relevant as per packing policy

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

Case No.	281 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	BLUE JET HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003358AM23
RA File Number	03AX04002988 AM23
Licence No and Date	0311018145/25/09/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Complete and balanced chemical reaction showing molecular weight and percentage yield on molar basis. ii. Material balance for each step showing recovery of By-Products and unreacted raw materials. iii. Technical literature in support of yield envisaged. iv. Production/ Consumption data duly certified by GST.	

Case No.	282 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INDO AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003360AM23
RA File Number	03AX04003351 AM23
Licence No and Date	0311018148/25/09/2022

Norms Committee Decision:

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

Justification for quantity of raw material asked for with calculation and yield based on the chemistry.

Case No.	283 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003366AM23
RA File Number	03AX04003250 AM23
Licence No and Date	0311018155/25/09/2022

Norms Committee Decision:

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

- i. DML showing Approved Composition.**
- ii. Master Batch Formula.**

Case No.	284 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	KIRI INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003367AM23
RA File Number	08AX04001034 AM23
Licence No and Date	0811006099/26/09/2022

Norms Committee Decision:

Deferred for comments of TE.

Case No.	285 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003375AM23
RA File Number	31AX04000183 AM23

Licence No and Date	3111001712/26/09/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Nov/202223/14 dated 07/12/2022 against advance authorization No. 3111000158 dated 08/03/2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
MORPHOLINE (ORGANIC CHEMICAL)	1 kg	1	DIETHYLENE GLYCOL	1.279 kg
		2	AMMONIA ANHYDROUS	0.217 kg
		3	HYDROGEN	Not allowed, as it is procured indigenously.
		4	MORPHOLINE CATALYST	Not allowed as no catalogue is available.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	286 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003382AM23
RA File Number	31AX04000178 AM23
Licence No and Date	3111001714/26/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	287 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023													
HQ File Number	HQRNORM APPLY 00003383AM23													
RA File Number	34AX04000610 AM23													
Licence No and Date	3411002827/26/09/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No NC/3/MEET/Nov/202223/12 dated 18/11/2022 against advance authorization No. 3411002081 dated 31/03/2022, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>Phenol</td> <td>1 MT</td> <td>1</td> <td>Cumene</td> <td>0.84466 MT</td> </tr> </tbody> </table>					Export product	Qty.	Sl. No.	Import items	Qty.	Phenol	1 MT	1	Cumene	0.84466 MT
Export product	Qty.	Sl. No.	Import items	Qty.										
Phenol	1 MT	1	Cumene	0.84466 MT										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	288 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003389AM23
RA File Number	08AX04001054 AM23
Licence No and Date	0811006114/26/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	289 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003417AM23
RA File Number	09AX04000478 AM23
Licence No and Date	0911003707/27/09/2022
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	290 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003393AM23
RA File Number	03AX04003371 AM23
Licence No and Date	0311018189/27/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jan/202021/4 dated 12/02/2021** against advance authorization No. **0310835448 dated 17/03/2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export Product	Qty.	Sl. No.	Import items	Qty.
CLARITHROMYCIN GRANULES 27.5%	1 kg	1	CLARITHROMYCIN	0.2727 kg
		2	ACETONE	1.00 kg

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

Case No.	291 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003395AM23
RA File Number	34AX04000620 AM23
Licence No and Date	3411002830/27/09/2022

Norms Committee Decision:

Deferred for comments of TE.

Case No.	292 / NC/3/MEET/Jan/202223/18
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Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003409AM23
RA File Number	07AX04000935 AM23
Licence No and Date	0711005338/27/09/2022
Norms Committee Decision:	
Deferred for comments of TE	

Case No.	293 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	GUJARAT FLUOROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003434AM23
RA File Number	34AX04000334 AM23
Licence No and Date	3411002838/28/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	294 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	AMNEAL INJECTABLES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003479AM23
RA File Number	08AX04000835 AM23
Licence No and Date	0811006153/30/09/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	295 / NC/3/MEET/Jan/202223/18
Case Status	Case Deferred
Party Name	ALCHEMIE FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003491AM23
RA File Number	03AX04002329 AM23
Licence No and	0311018301/30/09/2022

Date	
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	296 / NC/3/MEET/Jan/202223/18
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Jan/ 202223/ 18 and 23/01/2023
HQ File Number	HQRNORM APPLY 00003492AM23
RA File Number	03AX04003278 AM23
Licence No and Date	0311018302/30/09/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/9 dated 07/10/2022** against advance authorization No. **0311011646 dated 22/02/2022** , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Benzydamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and(other flavours. Each lozenge contains (i) Benzydamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride- 1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 31.034 Kgs (ii) 13.759 Kgs (iii) 26751.736 Kgs.)	1000 Number	1	Benzydamine Hydrochloride	3.06 gram
			2	Cetylpyridinium Chloride	1.356 gram
			3	Isomalt ST-M	2586.00 gram
2	Benzydamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-Inflammatory, Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg. Net content (i) 25.926 Kgs. (ii) 22348.129 Kgs.)	1000 Number	4	Benzydamine Hydrochloride	3.06 gram
			5	Isomalt ST-M	2586.00 gram
3	Benzydamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free.(Each lozenge contains (i)	1000 Number	6	Benzydamine Hydrochloride	3.06 gram

	Benzydamine Hydrochloride- 3mg (ii) Isomalt ST-M - 2586mg. Net content (i) 13.333 Kgs. (ii) 11493.343 Kgs.)		7	Isomalt ST-M	2586.00 gram
4	Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 1.968 Kg (ii) 3825.997 Kg.)	1000 Number	8	Cetylpyridinium Chloride	1.356 gram
			9	Isomalt ST-M	2586.00 gram
5	Cetylpyridinium Chloride And Benzydamine Hydrochloride Antiseptic Lozenges Sugar Free.(Each lozenge contains (i) Cetylpyridinium Chloride- 1 mg (ii) Isomalt ST-M - 2586mg. Net content (i) 1.333 Kg (ii) 3448.028 Kg)	1000 Number	10	Cetylpyridinium Chloride	1.02 gram
			11	Isomalt ST-M	2586.00 gram

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