



Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

Directorate General of Foreign Trade / विदेश व्यापार महानिदेशालय

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

VANIJA BHAWAN, AKBAR ROAD, NEW DELHI / 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/Nov/202223/14

DATED: 07/12/2022

Please Note

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

Meeting No. NC/3/MEET/Nov/202223/14 dated 07/12/2022 of Norms Committee - III for the year 2022-23 was held on 07/12/2022 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	Directorate General of Foreign Trade, Delhi
2	NAND Lal, Technical Authority	Technical Consultant, DGFT
3	SHAISH KUMAR, Technical Authority	Technical Consultant, DGFT
4	DINESHNARAIN MATHUR, Technical Authority	Technical Consultant, DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	RISHABH METALS & CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003297AM23
RA File Number	039504000554 AM21
Licence No and Date	0311000111/null

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.
POLYAMINE DERIVATIVES (64% solid content)	1 kg	1	DICYANDIAMIDE 99.5% MIN	0.16 kg
		2	DETA (DIETHYLENE TRIAMINE)	0.051 kg
		3	EPICHLOROHYDRIN	0.03 kg
		4	POLYACRYLAMIDE	0.32 kg

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

Case No.	2 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	SCOTT EDIL PHARMACIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00004204AM23
RA File Number	222404000012 AM14
Licence No and Date	2210013838/10/05/2013

Norms Committee Decision:

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

under:

Export Product	Qty.	Sl. No.	Import Items	Qty.
Amoxycillin 500 mg Capsules	1 number	1	Amoxycillin Trihydrate BP/EP/USP	585.36 mg

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

Case No.	3 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	DAFFODIL PHARMACHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00001402AM23
RA File Number	082404000449 AM15
Licence No and Date	0810134978/31/03/2015
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was observed that the import item do not match with the COA now furnished by the firm. Hence, it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	4 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003288AM23
RA File Number	318304000178 AM16
Licence No and Date	3110066046/14/03/2016
Norms Committee Decision: The Committee considered the request of firm for revision of adhoc norms and it was decided to call for following information / documents from the firm:	

- i. **Actual Production / Consumption for the last three years duly certified by CA.**
- ii. **Complete technical details as per Annexure to Appendix 4E.**
- iii **Reason for very high consumption of Methanol in GST certificate.**

Case No.	5 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	ELPPE CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003433AM23
RA File Number	039404000036 AM18
Licence No and Date	0310812684/24/04/2017

Norms Committee Decision:

The Committee considered the request of firm for revision of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **10/82-ALC4/2017 dated 10.01.2018** against advance authorization No. **0310807534 dated 01.09.2016** and it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
5-HYDROXY ISOPHTHALIC ACID	1 kg	1	ISOPHTHALIC ACID	2.24 kg
		2	CAUSTIC SODA FLAKES	2.00 kg
		3	CAUSTIC POTASH FLAKES	1.80 kg

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

Case No.	6 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003284AM23
RA File Number	052404000446 AM18
Licence No and Date	0510405089/26/12/2017

Norms Committee Decision:

The Committee considered the request of firm for revision of adhoc norms and taking cue from **SION A-3151**, it was decided to revise adhoc norms as under:

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

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

Case No.	7 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003287AM23
RA File Number	318304000129 AM18
Licence No and Date	3110066979/13/02/2018

Norms Committee Decision:

The Committee considered the request of firm for revision of adhoc norms and it was decided to call for following information / documents from the firm:

- i. **Chemical name of DNOVO.**
- ii. **Reason for giving chemical reaction starting from Phenol, when import item is 2,6 Xylenol.**
- iii. **Complete justification for yield of reaction when theoretically it comes to 0.85 kg/kg of Production.**
- iv. **Production consumption data for last three years duly certified by GST.**

Case No.	8 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003343AM23
RA File Number	039404000911 AM18
Licence No and Date	0310819230/19/02/2018
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 alongwith sample of each import item and export item.

Case No.	9 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00004051AM23
RA File Number	092404000229 AM19
Licence No and Date	0910066775/26/10/2018

Norms Committee Decision:

The Committee considered the request of firm for revision of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No **NC/3/MEET/Sep/202223/7 dated 16/09/2022** against advance authorization No. **0910067519 dated 14/05/2019** and it was decided to revise adhoc norms as under:

Sl. No.	Export Product	Qty	Sl. No.	Import Items	Qty
1	Enoxaparin Sodium Injection 20mg Pre-filled Syringes	1 Number	1	Heparin Sodium	39.733 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
2	Enoxaparin Sodium Injection 40mg Pre-filled Syringes	1 Number	1	Heparin Sodium	79.466 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 11.55% wastage

			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
3	Enoxaparin Sodium Injection 60mg Pre-filled Syringes	1 Number	1	Heparin Sodium	119.187 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 10.85% wastage
			5	Plunger Rods	Net + 1.65% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
4	Enoxaparin Sodium Injection 80mg Pre-filled Syringes	1 Number	1	Heparin Sodium	158.93 mg
			2	Barrel Syringes	Net + 4.65% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
5	Enoxaparin Sodium Injection 120mg Pre-filled Syringes	1 Number	1	Heparin Sodium	238.40 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage

			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
6	Enoxaparin Sodium Injection 150mg Pre-filled Syringes	1 Number	1	Heparin Sodium	298.00 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
RA concerned may take further necessary action as per above decision of NC.					

Case No.	10 / NC/3/MEET/Nov/202223/14				
Case Status	Case Approved				
Party Name	VN CREATIVE CHEMICALS PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022				
HQ File Number	HQRNORM REVIW00004310AM23				
RA File Number	039504000692 AM19				
Licence No and Date	0310824780/29/10/2018				
Norms Committee Decision:					
The Committee considered the request of firm for revision of adhoc norms 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. 0310829915 dated 25/06/2019 and it was decided to revise adhoc norms as under:					

Tonalid	1 kg	1	D M B-1 (2, 3 Dimethyl 1 Butene)	0.896 kg
		2	Paracymene	0.750 kg

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

Case No.	11 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00004045AM23
RA File Number	092404000420 AM19
Licence No and Date	0910066931/03/12/2018

Norms Committee Decision:

T

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/202223/7 dated 16/09/2022** against advance authorization No. **0910067519 dated 14/05/2019** 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	Enoxaparin Sodium Injection 20mg Pre-filled Syringes	1 Number	1	Heparin Sodium	39.733 mg
			2	0.5ml Barrel Syringes	Net + 5% wastage
			3	0.5ml Needle Shield	Net to Net
			4	0.5ml Plunger Stoppers	Net + 12% wastage
			5	0.5ml Plunger Rods	Net + 2.5% wastage
			6	0.5ml Preventis Needle Shielding System	Net + 3% wastage

2	Enoxaparin Sodium Injection 40mg Pre-filled Syringes	1 Number	1	Heparin Sodium	79.466 mg
			2	0.5ml Barrel Syringes	Net + 5% wastage
			3	0.5ml Needle Shield	Net to Net
			4	0.5ml Plunger Stoppers	Net + 11.55% wastage
			5	0.5ml Plunger Rods	Net + 2.5% wastage
			6	0.5ml Preventis Needle Shielding System	Net + 3% wastage
3	Enoxaparin Sodium Injection 60mg Pre-filled Syringes	1 Number	1	Heparin Sodium	119.187 mg
			2	1 ml Barrel Syringes	Net + 5% wastage
			3	1 ml Needle Shield	Net to Net
			4	1 ml Plunger Stoppers	Net + 10.85% wastage
			5	1 ml Plunger Rods	Net + 1.65% wastage
			6	1 ml Preventis Needle Shielding System	Net + 3% wastage
4	Enoxaparin Sodium Injection 80mg Pre-filled Syringes	1 Number	1	Heparin Sodium	158.93 mg
			2	1 ml Barrel Syringes	Net + 4.65% wastage
			3	1 ml Needle Shield	Net to Net
			4	1 ml Plunger Stoppers	Net + 12% wastage
			5	1 ml Plunger Rods	Net + 2.5% wastage
			6	1 ml Preventis Needle Shielding System	Net + 3% wastage

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

Case No.	12 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00004052AM23
RA File Number	092404000419 AM19
Licence No and Date	0910066930/03/12/2018

Norms Committee Decision:

The Committee considered the request of firm for revision of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No **NC/3/MEET/Sep/202223/7 dated 16/09/2022** against advance authorization No. **0910067519 dated 14/05/2019** and it was decided to revise adhoc norms as under:

Sl. No.	Export Product	Qty	Sl. No.	Import Items	Qty
1	Enoxaparin Sodium Injection 20mg Pre-filled Syringes	1 Number	1	Heparin Sodium	39.733 mg
			2	0.5ml Barrel Syringes	Net + 5% wastage
			3	0.5ml Needle Shield	Net to Net
			4	0.5ml Plunger Stoppers	Net + 12% wastage
			5	0.5ml Plunger Rods	Net + 2.5% wastage
			6	0.5ml Preventis Needle Shielding System	Net + 3% wastage
2	Enoxaparin Sodium Injection 40mg Pre-filled Syringes	1 Number	1	Heparin Sodium	79.466 mg
			2	0.5ml Barrel Syringes	Net + 5% wastage
			3	0.5ml Needle Shield	Net to Net
			4	0.5ml Plunger Stoppers	Net + 11.55% wastage
			5	0.5ml Plunger Rods	Net + 2.5% wastage
			6	0.5ml Preventis Needle Shielding System	Net + 3% wastage

3	Enoxaparin Sodium Injection 60mg Pre-filled Syringes	1 Number	1	Heparin Sodium	119.187 mg
			2	1ml Barrel Syringes	Net + 5% wastage
			3	1ml Needle Shield	Net to Net
			4	1ml Plunger Stoppers	Net + 10.85% wastage
			5	1ml Plunger Rods	Net + 1.65% wastage
			6	1ml Preventis Needle Shielding System	Net + 3% wastage
4	Enoxaparin Sodium Injection 80mg Pre-filled Syringes	1 Number	1	Heparin Sodium	158.93 mg
			2	1ml Barrel Syringes	Net + 4.65% wastage
			3	1ml Needle Shield	Net to Net
			4	1ml Plunger Stoppers	Net + 12% wastage
			5	1ml Plunger Rods	Net + 2.5% wastage
			6	1ml Preventis Needle Shielding System	Net + 3% wastage

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

Case No.	13 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003496AM23
RA File Number	522404000068 AM19
Licence No and Date	5210042870/18/12/2018
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. **Copy of application at the time of issuance of Licence.**

Case No.	14 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	HEMA DYECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00001544AM23
RA File Number	039404001141 AM19
Licence No and Date	0310828400/16/04/2019
Norms Committee Decision: The Committee considered the request of firm for revision of adhoc norms and it was decided to call for following information / documents from the firm: i. As per details furnished Residue generation is 6.2% and Distilled Loss is 5.1%. Please clarify it ii. Production / Consumption data for last two years duly certified by GST.	

Case No.	15 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003269AM23
RA File Number	039504000851 AM20
Licence No and Date	0310833095/29/11/2019
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was observed that earlier the norms were ratified as per SION A - 412. 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.	16 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003267AM23
RA File Number	039504000902 AM20
Licence No and Date	0310833406/13/12/2019
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was observed that earlier the norms were ratified as per SION A - 412. 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.	17 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	CLARIANT INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	018205001343AM21
RA File Number	039404000110 AM21
Licence No and Date	0310836469/01/06/2020
Norms Committee Decision: Deferred for comments of TE.	

Case No.	18 / NC/3/MEET/Nov/202223/14				
Case Status	Case Approved				
Party Name	GLAND PHARMA LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022				
HQ File Number	HQRNORM REVIW00004050AM23				
RA File Number	092404000069 AM21				
Licence No and Date	0910068850/05/06/2020				
Norms Committee Decision:					
The Committee considered the request of firm for revision of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No NC/3/MEET/Sep/202223/7 dated 16/09/2022 against advance authorization No. 0910067519 dated 14/05/2019 and it was decided to revise adhoc norms as under:					
Sl. No.	Export Product	Qty	Sl. No.	Import Items	Qty

1	Low Molecular Weight Heparin Enoxaparin Sodium Injection 20mg Pre-filled Syringes	1 Number	1	Heparin Sodium	39.733 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Plunger Stoppers	Net + 12% wastage
			4	Plunger Rods	Net + 2.5% wastage
			5	Preventis Needle Shielding System	Net + 3% wastage
2	Enoxaparin Sodium Injection 30mg/0.3ML Pre-filled Syringes	1 Number	1	Heparin Sodium	59.6 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Plunger Stoppers	Net + 12% wastage
			4	Plunger Rods	Net + 2.5% wastage
			5	Preventis Needle Shielding System	Net + 3% wastage
3	Low Molecular Weight Heparin Enoxaparin Sodium Injection 80mg Pre-filled Syringes	1 Number	1	Heparin Sodium	158.93 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Plunger Stoppers	Net + 12% wastage
			4	Plunger Rods	Net + 2.5% wastage
			5	Preventis Needle Shielding System	Net + 3% wastage

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

Case No.	19 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00004055AM23
RA File Number	092404000070 AM21
Licence No and Date	0910068942/07/07/2020

Norms Committee Decision:

The Committee considered the request of firm for revision of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No **NC/3/MEET/Sep/202223/7 dated 16/09/2022** against advance authorization No. **0910067519 dated 14/05/2019** and it was decided to revise adhoc norms as under:

Sl. No.	Export Product	Qty	Sl. No.	Import Items	Qty
1	Enoxaparin Sodium Injection 100mg Pre-filled Syringes	1 Number	1	Heparin Sodium	198.664 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
2	Enoxaparin Sodium Injection 120mg Pre-filled Syringes	1 Number	1	Heparin Sodium	238.40 mg
			2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage
3	Enoxaparin Sodium	1 Number	1	Heparin Sodium	298.00 mg

	Injection 150mg Pre-filled Syringes		2	Barrel Syringes	Net + 5% wastage
			3	Needle Shield	Net to Net
			4	Plunger Stoppers	Net + 12% wastage
			5	Plunger Rods	Net + 2.5% wastage
			6	Preventis Needle Shielding System	Net + 3% wastage

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

Case No.	20 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00234858AM22
RA File Number	092404000482 AM21
Licence No and Date	0910069522/27/11/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No **NC/3/MEET/Sep/202223/9** dated **07/10/2022** against advance authorization No. **0910069418** dated **29/10/2020**, 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.
(1R,2R)-2-amino-6-(4-nitrophenyl)-1-phenylhex-5-yn-1-ol hydrochloride	1 kg	1	4-Pentyn-1-ol	1.22 kg
		2	Iodobenzene diacetate	4.78 kg
		3	Di-tert-butyl dicarbonate (Boc anhydride)	3.16 kg
		4	CDX-034 Lyophilized Enzyme Powder	0.030 kg

		5	Beta-Nicotinamide adenine dinucleotide phosphate Sodium salt (beta-NADP-Na)	0.008 kg
		6	P-Iodonitro benzene	0.904 kg

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

Case No.	21 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00049028AM21
RA File Number	07AA04006399 AM21
Licence No and Date	0711000171/28/12/2020
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.	22 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	YASH RASAYAN & CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00056208AM21
RA File Number	34AA04001756 AM21
Licence No and Date	3411000089/06/01/2021
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/Jun/202223/5 dated 08/07/2022 against advance authorization No. 3410044109 dated 27/04/2018, 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.
2-METHOXY BENZOIC ACID	1 kg	1	METHYL SALICYLATE	1.052 kg
		2	DIMETHYL SULPHATE	0.8717 kg

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

Case No.	23 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00057063AM21
RA File Number	03AA04015653 AM21
Licence No and Date	0311000731/07/01/2021

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.
NITROXOLINE (BP/USP)	1 kg	1	8 HYDROXY QUINOLINE	1.235 kg

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

Case No.	24 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003396AM23
RA File Number	08AA04006131 AM21
Licence No and	0811000317/08/01/2021

Date				
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.
Meropenem for Injection 1gm((Net Content of Export Items is 112.50 K.G.)) (Each vial contains Meropenem Trihydrate USP equivalent to Anhydrous Meropenem 1 gm)	1 Number	1	STERILE MIXTURE OF MEROPENEM AND SODIUM CARBONATE	1.29 gram
RA concerned may take further necessary action as per above decision of NC.				

Case No.	25 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00058376AM21
RA File Number	09AA04003607 AM21
Licence No and Date	0911000131/08/01/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	26 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	MACLEODS PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00066631AM21
RA File Number	03AA04019289 AM21

Licence No and Date	0311001091/20/01/2021			
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.
Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 3225.00 kgs Dolutegravir Sodium + 19350.00 kgs Tenofovir Disoproxil Fumarate + 19350.00 kgs Lamivudine))	1 Number	1	(R)-3-Amino butan-1-ol	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	9-(R)-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.	27 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00067524AM21
RA File Number	07AA04007364 AM21
Licence No and Date	0711000345/21/01/2021
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.
CLOMIPRAMINE HCL (BP/EP/USP/JP)	1 kg	1	1 BROMO 3 CHLORO PROPANE	0.85 kg
		2	IMINODIBENZYL	1.00 kg
		3	METHANOL	1.20 kg
		4	IPA	0.50 kg
		5	TOLUENE	0.50 kg
		6	ACETONE	1.00 kg

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

Case No.	28 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	MACLEODS PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00070745AM21
RA File Number	03AA04020126 AM21
Licence No and Date	0311001263/27/01/2021

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.
Lamivudine 300mg + Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets(Lamivudine 300mg +	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

Tenofovir disoproxil Fumarate 300mg + Dolutegravir Sodium 50mg tablets (Net content: 17160.00 kgs Lamivudine + 17160.00 kgs Tenofovir Disoproxil Fumarate + 2860.00 kgs Dolutegravir Sodium))		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.	29 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00071643AM21
RA File Number	07AA04007643 AM21
Licence No and Date	0711000370/28/01/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	30 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00082860AM21
RA File Number	092404000486 AM21
Licence No and Date	0911000238/12/02/2021
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	Amoxycilin Capsules 250 mg (Each capsule containing Amoxycillin Trihydrate equivalent to 250 mg of Amoxycillin))	1 Number	1	6-APA (6-Amino Penicillanic Acid)	162.50 mg
			2	Methyl d-(-)-4-hydroxy-phenylglycinate OR D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester].	140.93 mg
			3	Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)	0.50 mg
2	Amoxycilin Capsules 500 mg (Each capsule containing Amoxycillin Trihydrate equivalent to 500 mg of Amoxycillin))	1 Number	1	6-APA (6-Amino Penicillanic Acid)	325.00 mg
			2	Methyl d-(-)-4-hydroxy-phenylglycinate OR D-(-)-4-hydroxyphenylglycine methyl ester [PHPG Ester].	281.86 mg
			3	Penicillin G Amidase (Particle size 250 - 500 micron, Creamish to Brown regularly shaped beads)	1.00 mg

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

Case No.	31 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003397AM23
RA File Number	08AA04008543 AM21
Licence No and Date	0811000672/15/02/2021

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:

Export product	Qty.	Sl. No.	Import items	Qty.
MEROPENEM FOR INJECTION 1GM USP/ BP/ IP/ CEP/ EP/ ChP ((NET CONTENT OF EXPORT ITEM IS 110 K.G.)) (Each vial contains Meropenem Trihydrate USP equivalent to Anhydrous Meropenem 1 gm)	1 Number	1	STERILE MIXTURE OF MEROPENEM AND SODIUM CARBONATE	1.29 gram
RA concerned may take further necessary action as per above decision of NC.				

Case No.	32 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	DEEPAK NITRITE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00085836AM21
RA File Number	34AA04001557 AM21
Licence No and Date	3411000043/17/02/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	33 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00087487AM21
RA File Number	08AA04009727 AM21
Licence No and Date	0811000726/19/02/2021
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:	

trimethylolpropane)(Chemicals)		2	Epichlorohydrin	0.995 kg
		3	Caustic Soda Lye 48 percentage	0.41 kg
		4	Toluene	Not allowed as no details shown in the process.

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

Case No.	34 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	SPEED INTERNATIONAL (INDIA) PRIAVTE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00089812AM21
RA File Number	03AA04022711 AM21
Licence No and Date	0311001589/23/02/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	35 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	SHREE MAHADEV INTERMEDIATE
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00090280AM21
RA File Number	34AA04002739 AM21
Licence No and Date	3411000251/23/02/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case.	

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

Case No.	36 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00092003AM21
RA File Number	038504000144 AM21
Licence No and Date	0311000450/25/02/2021

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. Taking into consideration molecular weight of Acetic Acid as 60 and 2 Moles are used to produce 1 Mole of Export have molecular weight 158.20. Therefore yield should be 0.76 kg /kg and taking 96% yield, the consumption should be 0.79 kg/kg, as compared to 1.210 kg. Please clarify it.**

Case No.	37 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00098861AM21
RA File Number	31AA04006764 AM21
Licence No and Date	3111000201/08/03/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No **NC/3/MEET/Mar/202122/15 dated 17/03/2022** against advance authorization No. **3111000148 dated 09-02-2021**, 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.
ETHYLENE DI AMINE (ORGANIC CHEMICAL)	1 kg	1	MONO ETHANOL AMINE	1.0374 kg
		2	AMMONIA ANHYDROUS	Not allowed, as it is

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

Case No.	38 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00098900AM21
RA File Number	31AA04006116 AM21
Licence No and Date	3111000158/08/03/2021

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/202223/8 dated 23/09/2022** against advance authorization No. **3111000445 dated 08/07/2021**, 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:

Export product	Qty.	Sl. No.	Import items	Qty.
MORPHOLINE	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.	39 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00098795AM21
RA File Number	03AA04028082 AM21
Licence No and Date	0311002315/08/03/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	40 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00098842AM21
RA File Number	03AA04028081 AM21
Licence No and Date	0311002319/08/03/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	41 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	DISCOVERY LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00100529AM21
RA File Number	092404000465 AM21
Licence No and Date	0911000490/10/03/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on	

DGFT Portal. Hence, the Committee decided to **reject** the case.

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

Case No.	42 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	LUPIN LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00103407AM21
RA File Number	03AA04019762 AM21
Licence No and Date	0311002479/15/03/2021
Norms Committee Decision:	
The firm has furnished its reply on DGFT Portal stating that the subject Advance Authorization falls under para 4.18 of HBP Vol. I (Non-Infringing Process) and hence they should be exempted from approval of NC.	
In view of above, the Committee decided to verify the same from RLA, Mumbai.	

Case No.	43 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00104575AM21
RA File Number	52AA04007931 AM21
Licence No and Date	5211000485/16/03/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	44 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	THERAPIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00104605AM21
RA File Number	09AA04005655 AM21
Licence No and Date	0911000535/16/03/2021
Norms Committee Decision:	

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

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

Case No.	45 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00106311AM21
RA File Number	09AA04004395 AM21
Licence No and Date	0911000512/18/03/2021

Norms Committee Decision:

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

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

Case No.	46 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	REYAANSH HEALTHCARE
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00107278AM21
RA File Number	03AA04022151 AM21
Licence No and Date	0311002655/19/03/2021

Norms Committee Decision:

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

DML for Export Product No. 1 and 2.

Case No.	47 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	WEST BENGAL CHEMICAL INDUSTRIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022

HQ File Number	HQRNORM APPLY 00107455AM21
RA File Number	02AA04010857 AM21
Licence No and Date	0211000433/19/03/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	48 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00107042AM21
RA File Number	03AA04029353 AM21
Licence No and Date	0311002597/19/03/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	49 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00109027AM21
RA File Number	03AA04031482 AM21
Licence No and Date	0311002729/22/03/2021
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. Percentage yield at every stage of reaction. ii. Stoichiometric balance on molar basis and percentage yield to arrive at the quantity of raw material asked	

for.

iii. Function of Acetaldoxime in the reaction.

iv. Justification for low yield in overall reaction, that is, 36%

v. Production / Consumption data for last one year duly certified by GST.

Case No.	50 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00114107AM21
RA File Number	09AA04005572 AM21
Licence No and Date	0911000481/26/03/2021

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.
Azathioprine 50mg	3000000 Numbers	1	Azathioprine	150 kg
		2	Cellulose Microcrystalline	150 kg
		3	Mannitol	150 kg
		4	Corn Starch	42 kg
		5	Croscarmellose Sodium	16.5 kg
		6	Povidone K	24 kg
		7	Sodium Stearyl Fumarate	7.5 kg
		8	Hypromellose	6.9 kg
		9	Macrogol	1.2 kg

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

Case No.	51 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00114387AM21
RA File Number	03AA04029354 AM21
Licence No and Date	0311002596/26/03/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	52 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00114423AM21
RA File Number	09AA04006434 AM21
Licence No and Date	0911000598/26/03/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	53 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00115936AM21
RA File Number	09AA04006613 AM21
Licence No and Date	0911000627/29/03/2021

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.
Dronedarone HCL (pharmaceutical product)	1 kg	1	Salicylaldehyde	1.00 kg
		2	Dimethyl formamide	1.00 kg
		3	Methylenedichloride	15.00 kg
		4	Iso propyl Alcohol	4.60 kg
		5	Di-n-butylamine	0.667 kg
		6	Methyl-2-bromo hexanoate	1.32 kg

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

Case No.	54 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00116713AM21
RA File Number	31AA04007907 AM21
Licence No and Date	3111000255/30/03/2021

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.
----------------	------	---------	--------------	------

AMINO ETHYL PIPERAZINE (ORGANIC CHEMICAL)	1 kg	1	MONO ETHANOL AMINE	1.07 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	55 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	VERTELLUS SPECIALTY MATERIALS (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00117102AM21
RA File Number	03AA04032376 AM21
Licence No and Date	0311002851/31/03/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	56 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00020260AM22
RA File Number	34AA04000021 AM22
Licence No and Date	3411000455/16/04/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Justification for 10% wastage.	

Case No.	57 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	BENZO CHEM INDUSTRIES PVT LTD

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022													
HQ File Number	HQRNORM REVIW00003258AM23													
RA File Number	03AA04000436 AM22													
Licence No and Date	0311003517/03/05/2021													
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: <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>PARA CHLORO PHENYL ACETIC ACID</td> <td>1 kg</td> <td>1</td> <td>PARA CHLORO BENZYL CYANIDE</td> <td>1.021 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.	PARA CHLORO PHENYL ACETIC ACID	1 kg	1	PARA CHLORO BENZYL CYANIDE	1.021 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
PARA CHLORO PHENYL ACETIC ACID	1 kg	1	PARA CHLORO BENZYL CYANIDE	1.021 kg										

Case No.	58 / NC/3/MEET/Nov/202223/14													
Case Status	Case Approved													
Party Name	BENZO CHEM INDUSTRIES PVT LTD													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022													
HQ File Number	HQRNORM REVIW00003257AM23													
RA File Number	03AA04000162 AM22													
Licence No and Date	0311003516/03/05/2021													
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: <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>PARA CHLORO PHENYL ACETIC ACID</td> <td>1 kg</td> <td>1</td> <td>PARA CHLORO BENZYL CYANIDE</td> <td>1.021 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.	PARA CHLORO PHENYL ACETIC ACID	1 kg	1	PARA CHLORO BENZYL CYANIDE	1.021 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
PARA CHLORO PHENYL ACETIC ACID	1 kg	1	PARA CHLORO BENZYL CYANIDE	1.021 kg										

Case No.	59 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003400AM23
RA File Number	08AA04010958 AM21
Licence No and Date	0811001148/20/05/2021

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:

Export product	Qty.	Sl. No.	Import items	Qty.
MEROPENEM FOR INJECTION 1GM USP/ BP/ CEP/IP/ EP/ ChP (Net Content of Export Item is 110 Kg)) (Each vial contains Meropenem Trihydrate USP equivalent to Anhydrous Meropenem 1 gm)	1 Number	1	STERILE MIXTURE OF MEROPENEM AND SODIUM CARBONATE	1.29 gram

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

Case No.	60 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003401AM23
RA File Number	08AA04002347 AM22
Licence No and Date	0811001626/01/06/2021

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	CEFTAZIDIME FOR INJECTION USP/BP/EP/CEP/IP/ChP 500MG (CEFTAZIDIME FOR INJECTION USP/BP/EP/CEP/IP/ChP 500MG. (NET CONTENT OF EXPORT ITEM IS 105KG))	1 Number	1	CEFTAZIDIME FOR INJECTION IP	0.550 grams
2	CEFTAZIDIME FOR INJECTION USP/BP/EP/CEP/IP/ChP 1GM (CEFTAZIDIME FOR INJECTION USP/BP/EP/CEP/IP/ChP 1GM (NET CONTENT OF EXPORT ITEM IS 150KG))	1 Number	2	CEFTAZIDIME FOR INJECTION IP	1.10 grams
3	CEFTAZIDIME FOR INJECTION USP/BP/EP/CEP/IP/ChP 2GM (CEFTAZIDIME FOR INJECTION USP/BP/EP/CEP/IP/ChP 2GM (NET CONTENT OF EXPORT ITEM IS 300KG))	1 Number	3	CEFTAZIDIME FOR INJECTION IP	2.20 grams

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

Case No.	61 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003402AM23
RA File Number	08AA04005392 AM22
Licence No and Date	0811001628/01/06/2021
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was decided to call for following information / documents from the firm: Master Batch Formula for export products.	

Case No.	62 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred

Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003403AM23
RA File Number	08AA04007143 AM22
Licence No and Date	0811001742/15/06/2021
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was decided to call for following information / documents from the firm: Master Batch Formula for export products.	

Case No.	63 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	INDORAMA VENTURES OXIDES ANKLESHWAR PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00116364AM22
RA File Number	03AA04018728 AM22
Licence No and Date	0311004668/16/06/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	64 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00122106AM22
RA File Number	03AA04032146 AM22
Licence No and Date	0311004837/23/06/2021
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:	

Export product	Qty.	Sl. No.	Import items	Qty.
NITROXOLINE	1 kg	1	8 HYDROXYQUINOLINE	1.235 kg

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

Case No.	65 / NC/3/MEET/Nov/202223/14			
Case Status	Case Approved			
Party Name	GOPINATH CHEM-TECH LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022			
HQ File Number	HQRNORM APPLY 00123213AM22			
RA File Number	08AA04009668 AM22			
Licence No and Date	0811001833/24/06/2021			
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.	66 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00123227AM22
RA File Number	09AA04005065 AM22
Licence No and Date	0911001102/24/06/2021
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:

Export product	Qty.	Sl. No.	Import items	Qty.
DRONEDARONE HCL (Pharmaceutical product)	1 kg	1	Salicylaldehyde	1.00 kg
		2	Dimethyl Formamide	1.00 kg
		3	Methylenedichloride	15.00 kg
		4	ISO Propyl Alcohol	4.60 kg
		5	Di N Butylamine	0.667 kg

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

Case No.	67 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	ZEE LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00124557AM22
RA File Number	05AA04028399 AM22
Licence No and Date	0511003336/25/06/2021

Norms Committee Decision:

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

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

Case No.	68 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022

HQ File Number	HQRNORM APPLY 00124729AM22
RA File Number	08AA04009431 AM22
Licence No and Date	0811001850/25/06/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	69 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00126124AM22
RA File Number	34AA04004372 AM22
Licence No and Date	3411000778/28/06/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	70 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	HIKAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00125843AM22
RA File Number	34AA04002140 AM22
Licence No and Date	3411000771/28/06/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	71 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022

and Date																				
HQ File Number	HQRNORM APPLY 00126786AM22																			
RA File Number	03AA04025749 AM22																			
Licence No and Date	0311005018/29/06/2021																			
Norms Committee Decision:																				
T																				
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.0310837390 dated 23.07.2020, 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 rowspan="4">METHYL - 3 - OXO - 2 - PENTYL - 1 - CYCLOPENTANE ACETATE</td> <td rowspan="4">1 kg</td> <td>1</td> <td>PENTYL ENDO (2 Pentyl-2-Cyclopentene -1-one)</td> <td>0.760 kg</td> </tr> <tr> <td>2</td> <td>DIMETHYL MALONATE</td> <td>0.660 kg</td> </tr> <tr> <td>3</td> <td>Sodium Methoxide</td> <td>0.120 kg</td> </tr> <tr> <td>4</td> <td>MS Barrel (Lacquered)</td> <td>Relevant as per packing policy</td> </tr> </tbody> </table>		Export Product	Qty.	Sl. No.	Import items	Qty.	METHYL - 3 - OXO - 2 - PENTYL - 1 - CYCLOPENTANE ACETATE	1 kg	1	PENTYL ENDO (2 Pentyl-2-Cyclopentene -1-one)	0.760 kg	2	DIMETHYL MALONATE	0.660 kg	3	Sodium Methoxide	0.120 kg	4	MS Barrel (Lacquered)	Relevant as per packing policy
Export Product	Qty.	Sl. No.	Import items	Qty.																
METHYL - 3 - OXO - 2 - PENTYL - 1 - CYCLOPENTANE ACETATE	1 kg	1	PENTYL ENDO (2 Pentyl-2-Cyclopentene -1-one)	0.760 kg																
		2	DIMETHYL MALONATE	0.660 kg																
		3	Sodium Methoxide	0.120 kg																
		4	MS Barrel (Lacquered)	Relevant as per packing policy																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	72 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	SCOTT EDIL PHARMACIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00127163AM22
RA File Number	30AA04008308 AM22
Licence No and Date	3011000821/30/06/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Department of Biotechnology	

(DBT) for obtaining their comments.

Case No.	73 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00129541AM22
RA File Number	03AA04033537 AM22
Licence No and Date	0311005080/02/07/2021

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 **NC/3/MEET/Oct/202122/9 dated 15/10/2021** against advance authorization No. **0310838214 dated 11-09-2020** 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	Clindamycin & Benzoyl Peroxide Gel 1percent/5percent (Pack Size 25gm)((Net Pack Wt. of Import Item Sr. No. 1 is 25.00 Kgs. & Sr. No. 2 is 125.00 Kgs.))	1 Number Pack	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)((Net Pack Wt. of Import Item Sr. No. 1 is 35.00 Kgs. & Sr. No. 2 is 175.00 Kgs.))	1 Number Pack	3	Clindamycin Phosphate USP	367.50 mg / pack
			4	HYDROUS BENZOYL PEROXIDE USP	1837.50 mg / pack
3	Clindamycin & Benzoyl Peroxide Gel 1percent/5percent (Pack Size 50gm)((Net Pack Wt. of Import Item Sr. No. 1 is 200.00 Kgs. & Sr. No. 2 is 1000.00 Kgs.))	1 Number Pack	5	Clindamycin Phosphate USP	525.00 mg / pack
			6	HYDROUS BENZOYL PEROXIDE USP	2625.00 mg / pack
4	Adapalene & Benzoyl Peroxide Gel 0.1percent/2.5percent (Pack Size 45gm)((Net Pack Wt. of Import Item Sr. No. 2 is 11.25 Kgs.))	1 Number Pack	7	HYDROUS BENZOYL PEROXIDE USP	1181.25 mg / pack

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

Case No.	74 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ORGANIC INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00129686AM22
RA File Number	06AA04003603 AM22
Licence No and Date	0611000533/02/07/2021
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. DML of each Export Product showing the Approved Composition. ii. COA of import item from foreign supplier.	

Case No.	75 / NC/3/MEET/Nov/202223/14				
Case Status	Case Approved				
Party Name	INDOCO REMEDIES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022				
HQ File Number	HQRNORM APPLY 00130667AM22				
RA File Number	03AA04041463 AM22				
Licence No and Date	0311005091/04/07/2021				
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:					
(A)					
Sl. No.	Export Product	Qty.	Sl. No.	Import Items	Qty.
1	ALLOPURINOL TABLETS 100MG (Each Allopurinol Tablet of 100mg	1 Number	1	Allopurinol	102.00 mg / 100 mg Tablet

	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) (Cross SION Norms of Allopurinol SION No.A2321 & Tablets/Capsules SION NoA412.))				
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) (Cross SION Norms of Allopurinol SION No.A2321 & Tablets/Capsules SION NoA412.))	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	Cyano Acetamide	0.60 kg

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

Case No.	76 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	DORF-KETAL CHEMICALS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00130670AM22
RA File Number	03AA04035632 AM22
Licence No and Date	0311005092/04/07/2021

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:

Export Product	Qty.	Sl. No.	Import Items	Qty.
Chemical Name Tetra n- Butyl Titanate Tyzor TNBT /D-140(Chemical Name Tetra n- Butyl Titanate Tyzor TNBT /D-140)	1 kg	1	Titanium Tetrachloride $TiCl_4$	0.57 kg
		2	N Butanol NBA Normal Butanol n Butyl Alcohol	0.90 kg
		3	Heptane Heptanes	0.20 kg

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

Case No.	77 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003426AM23
RA File Number	31AA04000987 AM22
Licence No and Date	3111000484/28/07/2021

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/Mar/202122/15 dated 17/03/2022** against advance authorization No. **3111000148 dated 09-02-2021**, 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.
DI ETHYLENE TRI AMINE ORGANIC CHEMICAL)	1 kg	1	MONO ETHANOL AMINE	1.0374 kg
		2	AMMONIA ANHYDROUS	Not allowed, as it is shown indigenous

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

Case No.	78 / NC/3/MEET/Nov/202223/14			
Case Status	Case Approved			
Party Name	BEST VALUE CHEM PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022			
HQ File Number	HQRNORM APPLY 00164145AM22			
RA File Number	34AA04006527 AM22			
Licence No and Date	3411000984/17/08/2021			
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.	79 / NC/3/MEET/Nov/202223/14			
Case Status	Case Deferred			
Party Name	HARMAN FINOCHEM LIMITED			
Meeting Number	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022			

and Date	
HQ File Number	HQRNORM APPLY 00164102AM22
RA File Number	03AA04065031 AM22
Licence No and Date	0311006216/17/08/2021
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 chemistry, molecular weight and percentage yield on molar basis for each step of manufacturing process. ii. Material balance for each step of manufacturing process.	

Case No.	80 / NC/3/MEET/Nov/202223/14													
Case Status	Case Approved													
Party Name	BEST VALUE CHEM PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022													
HQ File Number	HQRNORM APPLY 00164975AM22													
RA File Number	34AA04006491 AM22													
Licence No and Date	3411000985/18/08/2021													
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><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import Items</td><td>Qty.</td></tr><tr><td>Cyclo Hexyl Salicylate (Cyclohexyl-2-Hydroxy Benzoate)</td><td>1 kg</td><td>1</td><td>Methyl Salicylate</td><td>0.725 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty.	Cyclo Hexyl Salicylate (Cyclohexyl-2-Hydroxy Benzoate)	1 kg	1	Methyl Salicylate	0.725 kg
Export Product	Qty.	Sl. No.	Import Items	Qty.										
Cyclo Hexyl Salicylate (Cyclohexyl-2-Hydroxy Benzoate)	1 kg	1	Methyl Salicylate	0.725 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	81 / NC/3/MEET/Nov/202223/14			
Case Status	Case Deferred			
Party Name	ANTILA LIFESCIENCES PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022			
HQ File Number	HQRNORM APPLY 00165364AM22			

RA File Number	08AA04018980 AM22
Licence No and Date	0811002348/18/08/2021
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 of Export Product showing the Approved Composition.	

Case No.	82 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00165403AM22
RA File Number	05AA04062260 AM22
Licence No and Date	0511004178/18/08/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	83 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00165816AM22
RA File Number	05AA04070414 AM22
Licence No and Date	0511004197/18/08/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the quantity mentioned in the Advance Authorization against Export Product and import item is confusing. Hence, it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	84 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	SV PLASTOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00168909AM22
RA File Number	31AA04024928 AM22

Licence No and Date	3111000540/23/08/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	85 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	MANGALAM ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00169050AM22
RA File Number	03AA04027384 AM22
Licence No and Date	0311006375/23/08/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Specification of Export Product alongwith COA.	

Case No.	86 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	LITMUS ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00169051AM22
RA File Number	03AA04044240 AM22
Licence No and Date	0311006376/23/08/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case.	
RA concerned may take further necessary action as per above decision of NC.	

Case No.	87 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00169946AM22

RA File Number	03AA04066953 AM22			
Licence No and Date	0311006419/25/08/2021			
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.
2,4-DICHLOROBENZYL CYANIDE(N.A.)	1 kg	1	2 4 DICHLORO BENZYL CHLORIDE	1.154 kg
		2	SODIUM CYANIDE	0.286 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	88 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	SI GROUP - INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00170117AM22
RA File Number	03AA04063156 AM22
Licence No and Date	0311006435/25/08/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	89 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00170350AM22
RA File Number	03AA04069090 AM22
Licence No and Date	0311006443/25/08/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	90 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ATHENA DRUG DELIVERY SOLUTIONS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00170357AM22
RA File Number	03AA04069088 AM22
Licence No and Date	0311006444/25/08/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	91 / NC/3/MEET/Nov/202223/14													
Case Status	Case Approved													
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022													
HQ File Number	HQRNORM APPLY 00171241AM22													
RA File Number	31AA04025740 AM22													
Licence No and Date	3111000548/26/08/2021													
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/Mar/202122/15 dated 17/03/2022 against advance authorization No. 3111000148 dated 09-02-2021 , 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:														
<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 ETHYLENE TRI AMINE (ORGANIC CHEMICALS)</td><td rowspan="2">1 kg</td><td>1</td><td>MONO ETHANOL AMINE</td><td>1.0374 kg</td></tr><tr><td>2</td><td>AMMONIA ANHYDROUS</td><td>Not allowed, as it is shown indigenous</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	DI ETHYLENE TRI AMINE (ORGANIC CHEMICALS)	1 kg	1	MONO ETHANOL AMINE	1.0374 kg	2	AMMONIA ANHYDROUS	Not allowed, as it is shown indigenous
Export product	Qty.	Sl. No.	Import items	Qty.										
DI ETHYLENE TRI AMINE (ORGANIC CHEMICALS)	1 kg	1	MONO ETHANOL AMINE	1.0374 kg										
		2	AMMONIA ANHYDROUS	Not allowed, as it is shown indigenous										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	92 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	BENZO CHEM INDUSTRIES PVT LTD

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022			
HQ File Number	HQRNORM APPLY 00171413AM22			
RA File Number	50AA04002705 AM22			
Licence No and Date	0311006477/26/08/2021			
Norms Committee Decision:				
T				
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.
2,4-DICHLOROBENZYL CYANIDE(N.A.)	1 kg	1	2 4 DICHLORO BENZYL CHLORIDE	1.154 kg
		2	SODIUM CYANIDE	0.286 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	93 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	HARMONY ORGANICS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00171602AM22
RA File Number	31AA04024595 AM22
Licence No and Date	3111000549/26/08/2021
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. Yield of reactions giving justification / reason for low yield. ii. Stoichiometric balance between import and export on molar basis.	

Case No.	94 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	IPCA LABORATORIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022			
HQ File Number	HQRNORM APPLY 00172940AM22			
RA File Number	03AA04051423 AM22			
Licence No and Date	0311006518/28/08/2021			
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.
FRUSEMIDE / FUROSEMIDE	1 kg	1	Lasamide	0.910 kg
		2	Furfurylamine	1.207 kg
		3	Iso Propyl Alcohol	1.00 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	95 / NC/3/MEET/Nov/202223/14			
Case Status	Case Approved			
Party Name	SRIAM LABS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022			
HQ File Number	HQRNORM APPLY 00173574AM22			
RA File Number	09AA04010955 AM22			
Licence No and Date	0911001455/30/08/2021			
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. 0911002609 dated 03/03/2022 , 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.	Import items	Qty.

		No.		
(R)-2-(Diphenylmethyl) pyrrolidine hydrochloride (RDPH-II)	1 kg	1	D-Proline/R-Proline	1.167 kg

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

Case No.	96 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	BHARAT PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00175489AM22
RA File Number	34AA04006862 AM22
Licence No and Date	3411001052/02/09/2021

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.
CEFACLOX CAPSULES USP 500MG((EACH HARD GELATIN CAPSULE CONTAIN CEFACLOX USP EQ TO ANHYDROUS CEFACLOX 500MG)(TOTAL CONTENT: CEFACLOX IP/BP/USP 100.005 KGS)200010 Capsules)	200010 Number of Capsules	1	CEFACLOX	102 kg

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

Case No.	97 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00175852AM22

RA File Number	34AA04006370 AM22
Licence No and Date	3411000952/02/09/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	98 / NC/3/MEET/Nov/202223/14										
Case Status	Case Approved										
Party Name	UNIMAX CHEMICALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022										
HQ File Number	HQRNORM APPLY 00176177AM22										
RA File Number	03AA04077623 AM22										
Licence No and Date	0311006660/03/09/2021										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to ratify adhoc norms as under:											
<table><tr><td>Sl. No.</td><td>Export Product</td><td>SION No.</td></tr><tr><td>1</td><td>Erythromycin Base/Erythromycin</td><td>A-215</td></tr><tr><td>2</td><td>Erythromycin Oxime Base (Erythromycin A-9 Oxime)</td><td>A-2244</td></tr></table>			Sl. No.	Export Product	SION No.	1	Erythromycin Base/Erythromycin	A-215	2	Erythromycin Oxime Base (Erythromycin A-9 Oxime)	A-2244
Sl. No.	Export Product	SION No.									
1	Erythromycin Base/Erythromycin	A-215									
2	Erythromycin Oxime Base (Erythromycin A-9 Oxime)	A-2244									
RA concerned may take further necessary action as per above decision of NC.											

Case No.	99 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	BAZAYAN ENTERPRISES LLP
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM REVIW00003373AM23
RA File Number	03AA04078009 AM22
Licence No and Date	0311008047/29/10/2021
Norms Committee Decision:	
The Committee considered the request of firm for fixation of adhoc norms and it was decided to call for following information / documents from the firm:	

Particle size of import and export item may be indicated, supported by COA of export item and COA of import item from foreign supplier.

Case No.	100 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	OPES HEALTH CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00300023AM22
RA File Number	08AX04000140 AM22
Licence No and Date	0811003577/28/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply on DGFT Portal. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	101 / NC/3/MEET/Nov/202223/14																		
Case Status	Case Approved																		
Party Name	ALEMBIC PHARMACEUTICALS LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022																		
HQ File Number	HQRNORM APPLY 00301053AM22																		
RA File Number	34AX04000076 AM22																		
Licence No and Date	3411001604/29/12/2021																		
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><tr><td>Sl. No.</td><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>1</td><td>Duloxetine Caps.20 mg (Duloxetine Caps.20 mg (Net content of active ingredients 110.000 kgs))</td><td>1 Number Capsule</td><td>1</td><td>Duloxetine Hydrochloride Ph,Eur.</td><td>22.88 mg</td></tr><tr><td></td><td></td><td></td><td>2</td><td>Sugar Spheres (30-35 PHARM-A-SPHERES)</td><td>20.33 mg</td></tr></table>		Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.	1	Duloxetine Caps.20 mg (Duloxetine Caps.20 mg (Net content of active ingredients 110.000 kgs))	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	22.88 mg				2	Sugar Spheres (30-35 PHARM-A-SPHERES)	20.33 mg
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.														
1	Duloxetine Caps.20 mg (Duloxetine Caps.20 mg (Net content of active ingredients 110.000 kgs))	1 Number Capsule	1	Duloxetine Hydrochloride Ph,Eur.	22.88 mg														
			2	Sugar Spheres (30-35 PHARM-A-SPHERES)	20.33 mg														

			3	Hypromellose (Pharmacoat 606)	20.00 mg
			4	Talc (Luzenac Pharma Ultra Micronised grade)	12.63 mg
			5	Sucrose (Compressuc PS)	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 225.00 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.	102 / NC/3/MEET/Nov/202223/14				
Case Status	Case Approved				
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022				
HQ File Number	HQRNORM APPLY 00300536AM22				
RA File Number	03AX04000446 AM22				
Licence No and Date	0311009872/29/12/2021				
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/Nov/202223/12 dated 18.11.2022 against advance authorization No. 0311013691 dated 07.04.2022, 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:					

Moisture less than 500 PPM)			PURITY (Purity 98%)	
-----------------------------	--	--	---------------------	--

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

Case No.	103 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	SATYADIVIS PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00300935AM22
RA File Number	09AA04018000 AM22
Licence No and Date	0911002190/29/12/2021

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.
ALPHA-(2-METHYL AMINE) ETHYL BENZENE METHANOL	1 kg	1	BENZALDEHYDE	1.72 kg
		2	PALLADIUM	0.0004 kg
		3	PARAFORMALDEHYDE	0.40 kg
		4	ACETOPHENONE	1.63 kg

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

Case No.	104 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	HAFFKINE BIO PHARMACEUTICAL CORPORATION LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00301796AM22
RA File Number	03AX04000434 AM22

Licence No and Date	0311009905/30/12/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to refer the case to Department of Biotechnology (DBT) for obtaining their comments	

Case No.	105 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	KRUNAL INDUSTRIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00301989AM22
RA File Number	08AX04000162 AM22
Licence No and Date	0811003592/30/12/2021
Norms Committee Decision: Deferred for comments of TE.	

Case No.	106 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	CLARIANT INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00302256AM22
RA File Number	03AX04000499 AM22
Licence No and Date	0311009919/30/12/2021
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. Reason for giving nomenclature of Import Item No. 3 – Isononyl Acid Chloride in application whereas in the chemistry, it is Isononyl Chloride. ii. Yield of the total reaction with justification for high wastage. iii. Consumption coefficient for 1 kg of export product given in note, is quite different from quantity applied for. iv. Production / Consumption data alongwith indicating By-Product, if any with its value and evidence.	

Case No.	107 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00302260AM22

RA File Number	03AX04000308 AM22			
Licence No and Date	0311009920/30/12/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and 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. 0311004745 dated 19/06/2021, 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:				
Export product	Qty.	Sl. No.	Import items	Qty.
MEROPENEM FOR INJECTION (MEROPENEM BUFFERED STERILE)	1 kg	1	MEROPENEM NON STERILE MEROPENEM TRIHYDRATE NON STERILE	0.655 kg
		2	PACKING MATERIAL	Relevant as per packing policy
RA concerned may take further necessary action as per above decision of NC.				

Case No.	108 / NC/3/MEET/Nov/202223/14			
Case Status	Case Approved			
Party Name	OPTIMUS DRUGS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022			
HQ File Number	HQRNORM APPLY 00302605AM22			
RA File Number	09AX04000087 AM22			
Licence No and Date	0911002204/30/12/2021			
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/Mar/202122/16 dated 08/04/2022 against advance authorization No. 0911001704 dated 11-10-2021, 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:				
Export product	Qty.	Sl. No.	Import items	Qty.

VILDAGLIPTIN	1 kg	1	L-Proline	0.855 kg
		2	1-Adamantanamine Hydrochloride	0.904 kg
		3	DMF	0.50 kg
		4	Isopropyl alcohol	1.20 kg

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

Case No.	109 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00303773AM22
RA File Number	34AX04000113 AM22
Licence No and Date	3411001626/31/12/2021

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	Desipramine HCL Tab USP 10 mg(Desipramine HCL Tab USP 10 mg (net content of active ingredients = 3.50 kgs))	1 Number Tablet	1	Desipramine Hydrochloride USP	10.20 mg
			2	Croscarmellose Sodium (Ac-di-sol)	3.50 mg
			3	Microcrystalline cellulose (Avicel PH102)	13.41 mg
			4	Hydroxypropyl Cellulose (Klucel LF)	0.28 mg
			5	Citric Acid Monohydrate (Powder Emprove)	0.67 mg
			6	Magnesium Stearate	0.14 mg

2	Desipramine HCL Tab USP 25 mg(Desipramine HCL Tab USP 25 mg (net content of active ingredients = 8.750 kgs))	1 Number Tablet	1	Desipramine Hydrochloride USP	25.50 mg
			2	Croscarmellose Sodium (Ac-di-sol)	8.75 mg
			3	Microcrystalline cellulose (Avicel PH102)	33.53 mg
			4	Hydroxypropyl Cellulose (Klucel LF)	0.70 mg
			5	Citric Acid Monohydrate (Powder Emprove)	1.67 mg
			6	Magnesium Stearate	0.35 mg
3	Desipramine HCL Tab USP 50 mg(Desipramine HCL Tab USP 50 mg (net content of active ingredients = 20.00 kgs))	1 Number Tablet	1	Desipramine Hydrochloride USP	51.00 mg
			2	Croscarmellose Sodium (Ac-di-sol)	17.50 mg
			3	Microcrystalline cellulose (Avicel PH102)	67.07 mg
			4	Hydroxypropyl Cellulose (Klucel LF)	1.40 mg
			5	Citric Acid Monohydrate (Powder Emprove)	3.33 mg
			6	Magnesium Stearate	0.70 mg
4	Desipramine HCL Tab USP 75 mg(Desipramine HCL Tab USP 75 mg (net content of active ingredients = 30.000 kgs))	1 Number Tablet	1	Desipramine Hydrochloride USP	76.50 mg
			2	Croscarmellose Sodium (Ac-di-sol)	26.25 mg
			3	Microcrystalline cellulose (Avicel PH102)	100.60 mg
			4	Hydroxypropyl Cellulose (Klucel LF)	2.10 mg
			5	Citric Acid Monohydrate (Powder Emprove)	5.00 mg
			6	Magnesium Stearate	1.05 mg
5	Desipramine HCL Tab USP	1 Number	1	Desipramine Hydrochloride USP	102.00 mg

	100 mg(Desipramine HCL Tab USP 100 mg (net content of active ingredients = 40.00 kgs))	Tablet	2	Croscarmellose Sodium (Ac-di-sol)	35.00 mg
			3	Microcrystalline cellulose (Avicel PH102)	134.13 mg
			4	Hydroxypropyl Cellulose (Klucel LF)	2.80 mg
			5	Citric Acid Monohydrate (Powder Emprove)	6.67 mg
			6	Magnesium Stearate	1.40 mg
6	Desipramine HCL Tab USP 150 mg(Desipramine HCL Tab USP 150 mg (net content of active ingredients = 45.000 kgs))	1 Number Tablet	1	Desipramine Hydrochloride USP	153.00 mg
			2	Croscarmellose Sodium (Ac-di-sol)	52.50 mg
			3	Microcrystalline cellulose (Avicel PH102)	201.20 mg
			4	Hydroxypropyl Cellulose (Klucel LF)	4.20 mg
			5	Citric Acid Monohydrate (Powder Emprove)	10.00 mg
			6	Magnesium Stearate	2.10 mg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	110 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00303552AM22
RA File Number	07AX04000082 AM22
Licence No and Date	0711002772/31/12/2021
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. **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.	111 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00303629AM22
RA File Number	03AX04000191 AM22
Licence No and Date	0311009972/31/12/2021
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. Copy of DML for each export product. ii. Copy of Master Batch Formula for each export product.	

Case No.	112 / NC/3/MEET/Nov/202223/14			
Case Status	Case Approved			
Party Name	GRANULES INDIA LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022			
HQ File Number	HQRNORM APPLY 00306335AM22			
RA File Number	26AX04000010 AM22			
Licence No and Date	2611000396/03/01/2022			
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:				

		2	2R 3S 3 Tert Butoxy Carbonyl Amino 1 2 Epoxy 4 Phenyl Butane	0.43 kg
		3	Dichloromethane	4.41 kg
		4	Methoxycarbonyl L tert Leucine	0.60 kg
		5	N N Dicyclohexylcarbodiimide	0.79 kg
		6	Acetone	5.52 kg

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

Case No.	113 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	THEON PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00307355AM22
RA File Number	30AX04000052 AM22
Licence No and Date	3011001623/04/01/2022

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.
MEROPENEM FOR INJECTION USP 1 GM (EACH VIAL CONTAINS STERILE MEROPENEM EQ. TO ANHYDROUS MEROPENEM ALSO CONTAINS STERILE SODIUM CARBONATE (SODIUM 90.2 mg) ADDED AS BUFFER) (Each vial contains Meropenem Trihydrate USP equivalent to Anhydrous	1 Number	1	MEROPENEM FOR INJECTION USP	1.29 gram

Meropenem 1 gm)				
-----------------	--	--	--	--

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

Case No.	114 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00310531AM22
RA File Number	34AX04000034 AM22
Licence No and Date	3411001652/07/01/2022

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/202122/2 dated 02/07/2021** against advance authorization No. **3411000652 dated 31-05-2021**, 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
Hexyl Acetate	1 kg	1	n-Hexanol (Lorol C6/ Nacol 6)	0.782 kg

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

Case No.	115 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00310736AM22
RA File Number	05AX04000472 AM22
Licence No and Date	0511007713/07/01/2022

Norms Committee Decision:

Deferred for comments of TE.

Case No.	116 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	NAARI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00310737AM22
RA File Number	05AX04000473 AM22
Licence No and Date	0511007715/07/01/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	117 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00310788AM22
RA File Number	34AX04000140 AM22
Licence No and Date	3411001662/07/01/2022

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	Amantadine Hydrochloride capsules USP 100mg (Amantadine Hydrochloride capsules USP 100mg (Net content of active ingredients 270.00 kgs))	1 Number Capsule	1	Amantadine Hydrochloride USP	102.00 mg
			2	Microcrystalline cellulose (Avicel PH301)	106.00 mg
			3	Hydroxypropyl Cellulose (Klucel LF)	2.00 mg
			4	Croscarmellose Sodium (Ac-Di-Sol)	10.00 mg
			5	Colloidal Silicon Dioxide (Aerosil 200 Pharma)	1.00 mg
			6	Magnesium Stearate (Vegetable Source)	1.00 mg

			7	Empty Hard Gelatin Capsules Red Opaque / Red Opaque Size 2 imprinted with A226 on Cap in white ink	Relevant as per packing policy
2	Amantadine Hydrochloride Tablets USP 100mg (Amantadine Hydrochloride Tablets USP 100mg (Net content of active ingredients 300.00 kgs))	1 Number Tablet	1	Amantadine Hydrochloride USP	102.00 mg
			2	Microcrystalline Cellulose (Avicel PH 101)	33.65 mg
			3	Povidone (Kollidon 90F)	3.00 mg
			4	Lake Pigment HT 5285 FD&C Yellow 6 Sunset Yellow FCF Aluminum Lake	0.300 mg
			5	Sodium Starch Glycolate (Type A) (EXPLOTAB)	4.50 mg
			6	Povidone (K-30)	3.00 mg
			7	Colloidal Silicon Dioxide (Aerosil 200 Pharma)	0.75 mg
			8	Magnesium Stearate	0.80 mg

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

Case No.	118 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	SCITECH SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00311328AM22
RA File Number	03AA040131440 AM22
Licence No and Date	0311010245/07/01/2022

Norms Committee Decision:

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

Copy of DML with Approved Composition.

Case No.	119 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00313299AM22
RA File Number	03AX04000542 AM22
Licence No and Date	0311010308/10/01/2022

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. **0311013612 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:

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	1 Number	1	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg

	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.))	Tablet		Glycol Solvate USP	
			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)((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.))	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
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:

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

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

Case No.	120 / NC/3/MEET/Nov/202223/14				
Case Status	Case Approved				
Party Name	INTAS PHARMACEUTICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022				
HQ File Number	HQRNORM APPLY 00313838AM22				
RA File Number	08AX04000177 AM22				
Licence No and Date	0811003727/10/01/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from 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. 0811002920 dated 20/10/2021 , 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. (for 1 Number Vial)

1	METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number	1	METHOTREXATE EP / BP / IP / USP / PH. EUR.	55.00 mg
2	METHOTREXATE INJECTION BP 100MG/ML [5 ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100 MG)	1 Number	2	METHOTREXATE EP / BP / IP / USP / PH. EUR.	550.00 mg
3	METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL](EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)	1 Number	3	METHOTREXATE EP / BP / IP / USP / PH. EUR.	1100.00 mg
4	METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL](EACH ML CONTAINS: METHOTREXATE USP 25MG)	1 Number	4	METHOTREXATE EP / BP / IP / USP / PH. EUR.	275.00 mg
5	METHOTREXATE INJECTION BP 25MG/ML [20ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number	5	METHOTREXATE EP / BP / IP / USP / PH. EUR.	525.00 mg
6	METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number	6	METHOTREXATE EP / BP / IP / USP / PH. EUR.	1050.00 mg
7	METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 13.375 KGS.])	1 Number	7	METHOTREXATE EP / BP / IP / USP / PH. EUR.	5250.00 mg

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

Case No.	121 / NC/3/MEET/Nov/202223/14
Case Status	Case Rejected
Party Name	ASOJ SOFT CAPS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00313907AM22
RA File Number	34AX04000142 AM22
Licence No and Date	3411001665/10/01/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was observed that the import item No. 6 – Fish Oil (55 Percentage) (33:22) (Fish Lipid Oil) having ITC HS – 15042020 comes under Chapter 15 and as per para 4.11 (A) (i)

of the [FTP 2015-20](#) , all vegetable / edible oils classified under Chapter 15 of ITC (HS) are ineligible for import on self- declaration basis under para 4.07 of the FTP.

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.	122 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	PANACEA BIOTEC PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00314623AM22
RA File Number	05AX04000321 AM22
Licence No and Date	0511007823/11/01/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Department of Biotechnology (DBT) for obtaining their comments.	

Case No.	123 / NC/3/MEET/Nov/202223/14			
Case Status	Case Approved			
Party Name	UTTAM CAMPHOR WORKS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022			
HQ File Number	HQRNORM APPLY 00315086AM22			
RA File Number	06AA04008356 AM22			
Licence No and Date	0611001053/11/01/2022			
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.
CAMPHOR TABLETS (NET CONTENTS OF CAMPHOR POWER (SYNTHETIC) 9524 KGS.	10000 kg	1	CAMPHOR POWDER (SYNTHETIC)	9619.24 kg

FOR EXPORT OF 10000 KGS CAMPBOR TABLETS)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	124 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	PORUS LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00315693AM22
RA File Number	09AX04000098 AM22
Licence No and Date	0911002275/12/01/2022
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) End use of Export Product. (ii) Step wise manufacturing process. (iii) Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. (iv) Complete technical details as per Annexure to Appendix 4E for chemical products. (v) Stoichiometric balance between import and export on molar basis. (vi) Details of indigenous input with quantity.	

Case No.	125 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00315825AM22
RA File Number	09AX04000108 AM22
Licence No and Date	0911002281/12/01/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	126 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00317040AM22
RA File Number	08AX04000199 AM22
Licence No and Date	0811003776/13/01/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	127 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	VISWAAT CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00318314AM22
RA File Number	03AX04000704 AM22
Licence No and Date	0311010518/14/01/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
Information given for NVM in import and export is not matching since item of import at Sl. No. 1 – MIXED TERPENES AND TERPENOIDS IN AROMATIC SOLVENT [AS/01/031] is having 30% NVM and export is having 99.5% NVM.	

Case No.	128 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00318349AM22
RA File Number	31AX04000040 AM22
Licence No and Date	3111000876/14/01/2022
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. To give balanced chemical reaction of manufacturing of each export product giving Molecular weight with theoretical quantity and practical quantity obtained in the reaction.
- ii. Justification for low yield, if any.

Case No.	129 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00320005AM22
RA File Number	07AX04000209 AM22
Licence No and Date	0711002880/16/01/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	130 / NC/3/MEET/Nov/202223/14										
Case Status	Case Approved										
Party Name	DIAMINES AND CHEMICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022										
HQ File Number	HQRNORM APPLY 00321421AM22										
RA File Number	34AX04000074 AM22										
Licence No and Date	3411001688/17/01/2022										
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. 3411000643 dated 27/05/2021 , 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 Item Name.</td><td>Qty.</td></tr><tr><td>PIPERAZINE ANHYDROUS</td><td>1 kg</td><td>1</td><td>PIPERAZINE CRUDE OR PIPERAZINE MIXTURE (Percentage purity NMT 48.1%)</td><td>2.047 kg</td></tr></table>		Export Product	Qty	Sl. No.	Import Item Name.	Qty.	PIPERAZINE ANHYDROUS	1 kg	1	PIPERAZINE CRUDE OR PIPERAZINE MIXTURE (Percentage purity NMT 48.1%)	2.047 kg
Export Product	Qty	Sl. No.	Import Item Name.	Qty.							
PIPERAZINE ANHYDROUS	1 kg	1	PIPERAZINE CRUDE OR PIPERAZINE MIXTURE (Percentage purity NMT 48.1%)	2.047 kg							

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

Case No.	131 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00320688AM22
RA File Number	31AX04000045 AM22
Licence No and Date	3111000884/17/01/2022
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. Chemistry with yield. ii. Production / Consumption data duly certified by CA.	

Case No.	132 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00321040AM22
RA File Number	03AX04000043 AM22
Licence No and Date	0311010585/17/01/2022
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.	133 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022																
HQ File Number	HQRNORM APPLY 00321046AM22																
RA File Number	038504000145 AM21																
Licence No and Date	0311010587/17/01/2022																
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. 0311011997 dated 28/02/2022, 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 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">METHYL ACETOACETATE (ACETO ACETIC METHYL ESTER)</td> <td rowspan="2">1 kg</td> <td>1</td> <td>Acetic Acid</td> <td>1.209 kg (with 25% wastage)</td> </tr> <tr> <td>2</td> <td>Methanol</td> <td>0.284 kg (with 3% wastage)</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.	METHYL ACETOACETATE (ACETO ACETIC METHYL ESTER)	1 kg	1	Acetic Acid	1.209 kg (with 25% wastage)	2	Methanol	0.284 kg (with 3% wastage)
Export product	Qty.	Sl. No.	Import items	Qty.													
METHYL ACETOACETATE (ACETO ACETIC METHYL ESTER)	1 kg	1	Acetic Acid	1.209 kg (with 25% wastage)													
		2	Methanol	0.284 kg (with 3% wastage)													

Case No.	134 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	SWATI MENTHOL AND ALLIED CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00321275AM22
RA File Number	05AX04000573 AM22
Licence No and Date	0511007997/17/01/2022
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. As per process diagram, there is blending involved. ii. Item of Blending and its quantity.	

Case No.	135 / NC/3/MEET/Nov/202223/14
----------	-------------------------------

Case Status	Case Approved										
Party Name	SWATI MENTHOL AND ALLIED CHEMICALS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022										
HQ File Number	HQRNORM APPLY 00321279AM22										
RA File Number	05AX04000574 AM22										
Licence No and Date	0511007998/17/01/2022										
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/202122/2 dated 02/07/2021 against advance authorization No. 0511002498 dated 08/05/2021, 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>TRANS ANETHOLE DOUBLE DISTILLED 99.6 PERCENT TO 99.8 PERCENT</td> <td>155200 kg</td> <td>1</td> <td>ANETHOLE CONTAINING TRANS ANETHOLE 99 PERCENT</td> <td>156782 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.	TRANS ANETHOLE DOUBLE DISTILLED 99.6 PERCENT TO 99.8 PERCENT	155200 kg	1	ANETHOLE CONTAINING TRANS ANETHOLE 99 PERCENT	156782 kg
Export Product	Qty.	Sl. No.	Import items	Qty.							
TRANS ANETHOLE DOUBLE DISTILLED 99.6 PERCENT TO 99.8 PERCENT	155200 kg	1	ANETHOLE CONTAINING TRANS ANETHOLE 99 PERCENT	156782 kg							

Case No.	136 / NC/3/MEET/Nov/202223/14								
Case Status	Case Approved								
Party Name	OPTIMUS DRUGS PRIVATE LIMITED								
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022								
HQ File Number	HQRNORM APPLY 00322542AM22								
RA File Number	09AX04000129 AM22								
Licence No and Date	0911002311/18/01/2022								
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: <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.					

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.	137 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00323538AM22
RA File Number	09AX04000097 AM22
Licence No and Date	0911002338/19/01/2022
Norms Committee Decision:	
Deferred for comments of TE	

Case No.	138 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00324009AM22
RA File Number	03AX04000495 AM22
Licence No and	0311010688/19/01/2022

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. Molecular weight of Export Product. ii. Stoichiometric balance on molecular weight basis for second stage to arrive at the quantity of raw material asked for.	

Case No.	139 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00326435AM22
RA File Number	03AX04000846 AM22
Licence No and Date	0311010768/21/01/2022

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: (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) (Cross SION Norms of Allopurinol SION No.A2321 & Tablets/Capsules SION NoA412))	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	1 Number	2	Allopurinol	306.00 mg / 300 mg Tablet

0.0003mg ,Triethyl Ortho-formate 0.00063mg, Formamide 0.00045 mg, Morpholine 0.00039mg , Hydrazine Hydrate 0.00018 mg) (Cross SION Norms of Allopurinol SION No.A2321 & Tablets/Capsules SION NoA412.))				
--	--	--	--	--

(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	Cyano Acetamide	0.60 kg

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

Case No.	140 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00326509AM22
RA File Number	03AX04000816 AM22
Licence No and Date	0311010772/21/01/2022
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	Sodium Chloride 0.9% 100ml Infusion	1 Number	1	Sodium Chloride (SANAL)(EP)	0.945 gram
2	Sodium Chloride 0.9% 500ml Infusion	1 Number	2	Sodium Chloride (SANAL)(EP)	4.725 gram
3	Sodium Chloride 0.9% 1000ml Infusion	1 Number	3	Sodium Chloride (SANAL)(EP)	9.450 gram

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

Case No.	141 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00326841AM22
RA File Number	09AA04016329 AM22
Licence No and Date	0911002348/21/01/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	142 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00329136AM22
RA File Number	03AX04000717 AM22
Licence No and Date	0311010813/24/01/2022
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	143 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00329031AM22
RA File Number	09AX04000163 AM22
Licence No and Date	0911002351/24/01/2022

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.
Meropenem for Injection (Sterile Bulk) (containing NLT 84% Sterile Meropenem)	1 kg	1	Meropenem Trihydrate Non Sterile	0.8968 kg

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

Case No.	144 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00331260AM22
RA File Number	03AX04000915 AM22
Licence No and Date	0311010867/25/01/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call the firm for attending **Personal Hearing** before Norms Committee to explain its case alongwith following information / documents from the firm:

- i. **Description of all Excipients shown in items to be imported may be furnished as per their chemical**

name.

ii. Details of Packaging Material may be furnished.

iii. Copy of Master Batch Formula for export item indicating net content of inputs in each export.

Case No.	145 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00331317AM22
RA File Number	03AX04000937 AM22
Licence No and Date	0311010878/25/01/2022

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 **2/82-ALC4/2020 dated 10.07.2020** against advance authorization No. **0310835058 dated 25.02.2020**, 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.
FLUTICASONE LOTION 0.05 Percent (Pack 60 ML) (Net wt. of Fluticasone Propionate USP is 1.50 Kgs.)	50000 Numbers	1	Fluticasone Propionate USP	1.53 kg

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

Case No.	146 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	VISION DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00332326AM22
RA File Number	09AX04000156 AM22
Licence No and Date	0911002377/27/01/2022

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-ALC4/2019 dated 02.08.2019** against advance authorization No. **0910067431 dated**

01.05.2019, 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.
Piroctone Olamine (Pharmaceutical product)	1 kg	1	3,3-dimethylacrylic acid	0.84 kg
		2	Isononanoyl Chloride	1.30 kg
		3	Hydroxylamine Hcl	0.73 kg

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

Case No.	147 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00332964AM22
RA File Number	09AX04000151 AM22
Licence No and Date	0911002396/27/01/2022

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. **Name of the API produced from the export item stated to be a Drug – Intermediate.**
- ii. **Technical justification for the difference in the applied norms for FMP in the two licences taken in January 2022 and February 2022.**
- iii. **Foreign collaborators' Guaranteed Norms, if any, for the above export.**
- iv. **Copy of Technical Literature in support of yields claimed.**

Case No.	148 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00332998AM22

RA File Number	03AX04000818 AM22			
Licence No and Date	0311010921/27/01/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and on the basis of 90% yield 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.
Dimethyl-2-methyl glutarate	1 kg	1	2-methyl glutaronitrile (Purity 86-87%)	0.80 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	149 / NC/3/MEET/Nov/202223/14				
Case Status	Case Approved				
Party Name	INTAS PHARMACEUTICALS LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022				
HQ File Number	HQRNORM APPLY 00334092AM22				
RA File Number	08AX04000340 AM22				
Licence No and Date	0811003916/28/01/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from 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. 0811002920 dated 20/10/2021 , 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty. (for 1 Number Vial)
1	METHOTREXATE INJECTION BP 25MG/ML [2ML VIAL](EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number	1	METHOTREXATE EP / BP / IP / USP / PH. EUR.	55.00 mg
2	METHOTREXATE INJECTION BP 100MG/ML [5 ML	1 Number	2	METHOTREXATE EP / BP / IP /	550.00 mg

	VIAL)(EACH ML CONTAINS: METHOTREXATE PH. EUR 100 MG)			USP / PH. EUR.	
3	METHOTREXATE INJECTION BP 100MG/ML [10ML VIAL)(EACH ML CONTAINS: METHOREXATE PH. EUR. 100MG)	1 Number	3	METHOTREXATE EP / BP / IP / USP / PH. EUR.	1100.00 mg
4	METHOTREXATE INJECTION USP 25MG/ML [10ML VIAL)(EACH ML CONTAINS: METHOTREXATE USP 25MG)	1 Number	4	METHOTREXATE EP / BP / IP / USP / PH. EUR.	275.00 mg
5	METHOTREXATE INJECTION BP 25MG/ML [20ML VIAL)(EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number	5	METHOTREXATE EP / BP / IP / USP / PH. EUR.	525.00 mg
6	METHOTREXATE INJECTION BP 25MG/ML [40ML VIAL)(EACH ML CONTAINS: METHOTREXATE PH. EUR. 25MG)	1 Number	6	METHOTREXATE EP / BP / IP / USP / PH. EUR.	1050.00 mg
7	METHOTREXATE INJECTION BP 100MG/ML [50ML VIAL)(EACH ML CONTAINS: METHOTREXATE PH. EUR. 100MG [IN WHICH ACTIVE INGREDIENT METHOTREXATE USED IS 41.525 KGS.])	1 Number	7	METHOTREXATE EP / BP / IP / USP / PH. EUR.	5250.00 mg

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

Case No.	150 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	GLAND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00333745AM22
RA File Number	09AX04000069 AM22
Licence No and Date	0911002409/28/01/2022

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.
----------------	------	---------	--------------	------

Nadroparin Calcium Injection 5700 IU/0.6ml fill in 1ml PFS(Composition: Each Pre- Filled Syringe Contains: Nadroparin Calcium Ph.Eur.5700 IU, Water for Injection Ph.Eur. 'q.s. to 0.6ml)	1 Number	1	Nadroparin Calcium	52.25 mg
		2	Barrel Syringes	1.05 Numbers
		3	Plunger Stoppers	1.1085 Numbers
		4	Plunger Rods	1.0165 Numbers
		5	Preventis Needle Shielding System	1.05 Numbers

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

Case No.	151 / NC/3/MEET/Nov/202223/14
Case Status	Case Approved
Party Name	SYMED LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00333903AM22
RA File Number	09AX04000106 AM22
Licence No and Date	0911002414/28/01/2022

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.
3 - Cyno-2-ethoxy carbonyl -5- Methyl-hexanoic acid ethyl ester	1 kg	1	Iso Valeraldehyde	0.515 kg
		2	Di n Propyl Amine	0.070 kg
		3	Diethyl Malonate	0.870 kg

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

Case No.	152 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00343548AM22
RA File Number	31AX04000047 AM22
Licence No and Date	3111000999/04/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Chemistry with yield. ii. Production / Consumption data duly certified by CA.	

Case No.	153 / NC/3/MEET/Nov/202223/14																			
Case Status	Case Approved																			
Party Name	OPTIMUS DRUGS PRIVATE LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022																			
HQ File Number	HQRNORM APPLY 00342862AM22																			
RA File Number	09AX04000195 AM22																			
Licence No and Date	0911002452/04/02/2022																			
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><th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr><tr><td rowspan="4">6-Fluoro-3-hydroxypyrazine-2-carboxamide</td><td rowspan="4">1 kg</td><td>1</td><td>6-bromo-3-hydroxypyrazine-2-carboxamide</td><td>2.32 kg</td></tr><tr><td>2</td><td>Triethylamine</td><td>2.15 kg</td></tr><tr><td>3</td><td>NN Dimethylformamide</td><td>5.00 kg</td></tr><tr><td>4</td><td>Tri-n-butylamine</td><td>3.40 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	6-Fluoro-3-hydroxypyrazine-2-carboxamide	1 kg	1	6-bromo-3-hydroxypyrazine-2-carboxamide	2.32 kg	2	Triethylamine	2.15 kg	3	NN Dimethylformamide	5.00 kg	4	Tri-n-butylamine	3.40 kg
Export product	Qty.	Sl. No.	Import items	Qty.																
6-Fluoro-3-hydroxypyrazine-2-carboxamide	1 kg	1	6-bromo-3-hydroxypyrazine-2-carboxamide	2.32 kg																
		2	Triethylamine	2.15 kg																
		3	NN Dimethylformamide	5.00 kg																
		4	Tri-n-butylamine	3.40 kg																

		5	Dimethyl Sulfoxide	2.59 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	154 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	BALAJI AMINES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	NORM APPLY 00343126AM22
RA File Number	31AX04000059 AM22
Licence No and Date	3111000968/04/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Complete chemistry starting from import items with calculations based on molecular weight. ii. Yield of the reaction with justification for low yield, if any. iii. Production / Consumption data duly certified by GST.	

Case No.	155 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00343056AM22
RA File Number	34AX04000212 AM22
Licence No and Date	3411001750/04/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Complete chemistry giving molecular weight and percentage yield on molar basis for each step of manufacturing process. (ii) Application / function of Magnesium Turning.	

Case No.	156 / NC/3/MEET/Nov/202223/14
----------	-------------------------------

Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00343395AM22
RA File Number	03AX04001061 AM22
Licence No and Date	0311011086/04/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	157 / NC/3/MEET/Nov/202223/14																			
Case Status	Case Approved																			
Party Name	DANOPHARM CHEMICALS PRIVATE LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022																			
HQ File Number	HQRNORM APPLY 00343441AM22																			
RA File Number	039404000360 AM21																			
Licence No and Date	0311011114/04/02/2022																			
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="3">5-CHLORO-2-METHYL AMINO BENZOPHENONE (ANTI DEPRESSION)</td><td rowspan="3">1 kg</td><td>1</td><td>2 AMINO 5 CHLORO BENZOPHENONE</td><td>1.257 kg</td></tr><tr><td>2</td><td>POTASSIUM CARBONATE</td><td>0.750 kg</td></tr><tr><td>3</td><td>TETRABUTYL AMMONIUM HYDREGEN SULPHATE</td><td>0.100 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	5-CHLORO-2-METHYL AMINO BENZOPHENONE (ANTI DEPRESSION)	1 kg	1	2 AMINO 5 CHLORO BENZOPHENONE	1.257 kg	2	POTASSIUM CARBONATE	0.750 kg	3	TETRABUTYL AMMONIUM HYDREGEN SULPHATE	0.100 kg
Export product	Qty.	Sl. No.	Import items	Qty.																
5-CHLORO-2-METHYL AMINO BENZOPHENONE (ANTI DEPRESSION)	1 kg	1	2 AMINO 5 CHLORO BENZOPHENONE	1.257 kg																
		2	POTASSIUM CARBONATE	0.750 kg																
		3	TETRABUTYL AMMONIUM HYDREGEN SULPHATE	0.100 kg																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	158 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	INNOVASSYNTH TECHNOLOGIES (INDIA) LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00343443AM22
RA File Number	03AX04000895 AM22
Licence No and Date	0311011115/04/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	159 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	INNOVASSYNTH TECHNOLOGIES (INDIA) LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00343444AM22
RA File Number	03AX04000893 AM22
Licence No and Date	0311011116/04/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	160 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	INNOVASSYNTH TECHNOLOGIES (INDIA) LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00343445AM22
RA File Number	03AX04000892 AM22
Licence No and Date	0311011117/04/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	161 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00345204AM22
RA File Number	03AX04001106 AM22
Licence No and Date	0311011140/06/02/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and it was decided to call the firm for attending **Personal Hearing** before Norms Committee to explain its case alongwith following information / documents from the firm:

- i. **As per manufacturing process, molecular weight of finished product is 384.69, while as per catalogue attached, molecular weight is 150. Please explain it.**
- ii. **How in step 2, yield is more than 100%, that is, 121%.**
- iii. **Stoichiometric balance on molar basis to arrive at the quantity of raw material asked for.**

Case No.	162 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	INNOVASSYNTH TECHNOLOGIES (INDIA) LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00345730AM22
RA File Number	03AX04000898 AM22
Licence No and Date	0311011149/07/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	163 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00345828AM22
RA File Number	09AX04000205 AM22
Licence No and Date	0911002465/07/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	164 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	OLON ACTIVE PHARMACEUTICAL INGREDIENTS INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00345974AM22
RA File Number	03AX04001021 AM22
Licence No and Date	0311010996/07/02/2022
Norms Committee Decision:	

Deferred for comments of TE

Case No.	165 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00346268AM22
RA File Number	34AX04000204 AM22
Licence No and Date	3411001767/07/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	166 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	PUNISKA HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00347306AM22
RA File Number	08AX04000205 AM22
Licence No and Date	0811003993/08/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	167 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ARKRAY HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00347493AM22
RA File Number	52AX04000059 AM22
Licence No and Date	5211001995/08/02/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Department of Biotechnology (DBT) for obtaining their comments.	

Case No.	168 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00348248AM22
RA File Number	03AX04001105 AM22
Licence No and Date	0311011230/09/02/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith following information / documents from the firm: i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name. ii. Details of Packaging Material may be furnished. iii. Copy of Master Batch Formula for export item indicating net content of inputs in each export.	

Case No.	169 / NC/3/MEET/Nov/202223/14			
Case Status	Case Approved			
Party Name	DANOPHARM CHEMICALS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022			
HQ File Number	HQRNORM APPLY 00348260AM22			
RA File Number	039404000358 AM21			
Licence No and Date	0311000653/09/02/2022			
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.
Alpha-(2,4-Dichlorophenyl)-1H-Imidazole-1-Ehtanol(Anti Inflammatory)	1 kg	1	2 4 Dichloro Acetophenone	1.45 kg
		2	Imidazole	0.53 kg
		3	Sodium Borohydride	0.10 kg
		4	Dimethyl Sulphoxide	1.00 kg

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

Case No.	170 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	VENKATA NARAYANA ACTIVE INGREDIENTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00348986AM22
RA File Number	04AX04000023 AM22
Licence No and Date	0411002608/09/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	171 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00350237AM22
RA File Number	05AX04000943 AM22
Licence No and Date	0511008753/10/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	172 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	LAURUS SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00351303AM22
RA File Number	09AX04000191 AM22
Licence No and Date	0911002504/11/02/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Name of the API produced from the export item stated to be a Drug – Intermediate. ii. Technical justification for the difference in the applied norms for FMP in the two licences taken in	

January 2022 and February 2022.

iii. Foreign collaborators' Guaranteed Norms, if any, for the above export.

iv. Copy of Technical Literature in support of yields claimed.

Case No.	173 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	LAXMI ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00351870AM22
RA File Number	03AX04000936 AM22
Licence No and Date	0311011342/11/02/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call the firm for attending Personal Hearing before Norms Committee to explain its case alongwith following information / documents from the firm:	
i. As per manufacturing process, Acetic Acid is cracked to get Ketone as such other than obtained in cracking with their value. ii. Stoichiometric balance with molecular weight to arrive at the quantity of raw material asked for. iii. Production / Consumption data for last two years duly certified by GST.	

Case No.	174 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	PIL PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00356272AM22
RA File Number	05AX04000849 AM22
Licence No and Date	0511008550/15/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	175 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00356332AM22
RA File Number	08AX04000424 AM22
Licence No and	0811004069/15/02/2022

Date	
Norms Committee Decision:	
Deferred for comments of TE	

Case No.	176 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00356333AM22
RA File Number	08AX04000425 AM22
Licence No and Date	0811004071/15/02/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	177 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	VENUS REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00356345AM22
RA File Number	30AX04000119 AM22
Licence No and Date	3011001784/15/02/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
(i) Description of Export Product No. 2 – VINORELBINE SOLUTION FOR INJECTION (10MG/5ML) does not match with DML (ii) No DML is given for 1 ml vial.	

Case No.	178 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00355978AM22
RA File Number	03AX04001161 AM22
Licence No and Date	0311011414/15/02/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call the firm for attending **Personal Hearing** before Norms Committee to explain its case alongwith following information / documents from the firm:

- i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name.**
- ii. Details of Packaging Material may be furnished.**
- iii. Copy of Master Batch Formula for export item indicating net content of inputs in each export.**

Case No.	179 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00355981AM22
RA File Number	03AX04001160 AM22
Licence No and Date	0311011415/15/02/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to call the firm for attending **Personal Hearing** before Norms Committee to explain its case alongwith following information / documents from the firm:

- i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name.**
- ii. Details of Packaging Material may be furnished.**
- iii. Copy of Master Batch Formula for export item indicating net content of inputs in each export.**

Case No.	180 / NC/3/MEET/Nov/202223/14
Case Status	Case Deferred
Party Name	GANGWAL HEALTHCARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 14 and 07/12/2022
HQ File Number	HQRNORM APPLY 00356909AM22
RA File Number	03AX04001205 AM22
Licence No and Date	0311011422/16/02/2022

Norms Committee Decision:

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

- i. **Exact composition of Export Product.**
- ii. **COA of Export Product.**
- iii. **Percentage Assay of Import Item No. 1 – DHA (Docosahexaenoic Acid) is not mentioned in the Advance Authorization. Please clarify with amendment, if any.**
- iv. **COA of import Item No. 1 - DHA (Docosahexaenoic Acid).**