



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / व्यापार महकमा

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

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(DES - III SECTION)**MINUTES OF THE NORMS COMMITTEE- III****MEETING No.** NC/3/MEET/Nov/202223/12**DATED:** 18/11/2022Please 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/202223/12 dated 18/11/2022 of Norms Committee - III for the year 2022-23 was held on 18/11/2022 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/202223/12
Case Status	Case Rejected
Party Name	INCHEM LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00002967AM23
RA File Number	092404000044 AM15
Licence No and Date	0910059969/01/05/2014
Norms Committee Decision: The Committee considered the request of firm for review of adhoc norms and it was observed that the firm has not provided any technical data in support of its request. 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.	2 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	RIDDHI PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003951AM23
RA File Number	342404000266 AM15
Licence No and Date	3410040864/12/01/2015
Norms Committee Decision: The firm vide e-mail dated 01.11.2022 has informed that they are satisfied with the adhoc norms ratified by Norms Committee-3 in its Meeting No. 3/AM21 dated 02.09.2020 and hence they would like to withdraw their request. In view of above e-mail, the Committee decided to withdraw the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	3 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	ALKALOIDS CORPORATION
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00000462AM23
RA File Number	022404000145 AM17

Licence No and Date	0210207123/07/11/2016			
Norms Committee Decision:				
The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/202223/8 dated 23/09/2022 against advance authorization No. 0210207904 dated 24/10/2017 , it was decided to revise adhoc norms as under:				
Export product	Qty.	Sl. No.	Import items	Qty.
Papaverine Hydrochloride BP	1 kg	1	Papaverine Crude Content 95%	1.158 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	4 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	PAYAL POLYPLAST PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM REVIW00003159AM23			
RA File Number	052404000478 AM17			
Licence No and Date	0510401740/21/02/2017			
Norms Committee Decision:				
The Committee considered the request of firm for review 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.	5 / NC/3/MEET/Nov/202223/12
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Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00002756AM23
RA File Number	522404000085 AM18
Licence No and Date	5210042570/20/03/2018
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	6 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003008AM23
RA File Number	318304000171 AM18
Licence No and Date	3110067030/12/04/2018
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	7 / NC/3/MEET/Nov/202223/12
Case Status	Case Rejected
Party Name	PORUS LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003044AM23
RA File Number	092404000001 AM19
Licence No and Date	0910066235/15/05/2018
Norms Committee Decision:	
The Committee considered the request of firm for enhancement of in the quantity of import item No. 6 – Activated Carbon and it was observed that the firm has not provided any technical data in support of its request. 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.	8 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003137AM23
RA File Number	318304000005 AM19
Licence No and Date	3110067060/23/05/2018
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	9 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003005AM23
RA File Number	318304000081 AM19
Licence No and Date	3110067162/24/08/2018
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and it was decided to call for following information/documents from the firm:	
Quantity of Higher Methylated Phenol as a By-Product produced during reaction against 1 kg of Export and its Commercial Value alongwith sale invoice copy.	

Case No.	10 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	DCM SHRIRAM INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM REVIW00003431AM23			
RA File Number	052304000242 AM19			
Licence No and Date	0510407689/05/09/2018			
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:				

D (-) Alpha Phenyl Glycine Ethyl Potassium Dane Salt.	1 kg	1	D (-) Alpha Phenyl Glycine Base	0.512 kg
		2	Ethyl Aceto Acetate	0.409 kg
		3	Potassium Hydroxide	0.215 kg

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

Case No.	11 / NC/3/MEET/Nov/202223/12
Case Status	Case Rejected
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003183AM23
RA File Number	052404000392 AM19
Licence No and Date	0510408318/02/11/2018
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and it was observed that the firm has not provided any technical data in support of its request. 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.	12 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003070AM23
RA File Number	052404000473 AM19
Licence No and Date	0510408806/06/12/2018
Norms Committee Decision:	
The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. 13/82-ALC4/2018 dated 14.01.2019 against advance authorization No. 0510407655 dated 31.08.2018 , it was decided to revise adhoc norms as under:	

Export product	Qty.	Sl. No.	Import items	Qty.
PLASTICIZER (PVC) (DI-OCTYL TERAPHTHALATE (DOTP))	1 kg	1	PURE TERE PHTHALIC ACID	0.447 kg
		2	2 ETHYL HEXANOL	0.680 kg

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

Case No.	13 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MALLADI DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00002622AM23
RA File Number	042404000143 AM19
Licence No and Date	0410164962/10/12/2018

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and it was observed that the norms applied by the firm are higher than supported by the chemistry and material balance. Also, the Export Product is a new molecule.

Hence, it was decided to call the firm for attending **Personal Hearing** before Norms Committee to explain its case.

Case No.	14 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003104AM23
RA File Number	052404000511 AM19
Licence No and Date	0510408987/19/12/2018

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **13/82-ALC4/2018 dated 14.01.2019** against advance authorization No. **0510407655 dated 31.08.2018**, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
PLASTICIZER (PVC) (DOTP)	1 kg	1	PURE TERA PHTHALIC ACID	0.447 kg
		2	2 ETHYL HEXANOL	0.680 kg

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

Case No.	15 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00002987AM23
RA File Number	318304000157 AM19
Licence No and Date	3110067278/09/01/2019

Norms Committee Decision:

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

Quantity of Higher Methylated Phenol as a By-Product produced during reaction against 1 kg of Export and its Commercial Value alongwith sale invoice copy.

Case No.	16 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00002822AM23
RA File Number	052404000650 AM19
Licence No and Date	0510409704/20/02/2019

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **13/82-ALC4/2018 dated 14.01.2019** against advance authorization No. **0510407655 dated 31.08.2018**, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
PVC PLASTICIZER (DOTP)	1 kg	1	PURE TERA PHTHALIC ACID	0.447 kg
		2	2 ETHYL HEXANOL	0.680 kg

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

Case No.	17 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003142AM23
RA File Number	052404000647 AM19
Licence No and Date	0510409744/22/02/2019

Norms Committee Decision:

The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. **13/82-ALC4/2018 dated 14.01.2019** against advance authorization No. **0510407655 dated 31.08.2018**, it was decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
PVC PLASTICIZER (DOTP)	1 kg	1	Pure Tera Phthalic Acid	0.447 kg
		2	2 Ethyl Hexanol	0.680 kg

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

Case No.	18 / NC/3/MEET/Nov/202223/12
Case Status	Case Rejected
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003268AM23

RA File Number	039504001191 AM20
Licence No and Date	0310835417/17/03/2020
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.	19 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SRI CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00002991AM23
RA File Number	042404000109 AM21
Licence No and Date	0410167147/07/10/2020
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: 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. Export Product description mentioned in the Advance Authorization is in Brand Name. Please furnish exact chemical name of Export Product with its technical catalogue.	

Case No.	20 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SCOTT EDIL PHARMACIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00002997AM23
RA File Number	30AA04004572 AM21
Licence No and Date	3011000300/24/02/2021
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 its comments.

Case No.	21 / NC/3/MEET/Nov/202223/12
Case Status	Case Rejected
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003215AM23
RA File Number	03AA04025038 AM21
Licence No and Date	0311002397/10/03/2021
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.	22 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00002912AM23
RA File Number	05AA04041798 AM21
Licence No and Date	0511001982/01/04/2021
Norms Committee Decision: The Committee considered the request of firm for fixation of adhoc norms and it was observed that the norms applied are very high and no chemistry was given. Hence, it was decided to call for following information/documents from the firm: i. Complete chemistry, molecular weight, percentage yield on molar basis. ii Material balance for entire process.	

Case No.	23 / NC/3/MEET/Nov/202223/12
Case Status	Case Rejected
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003219AM23
RA File Number	03AA04033912 AM21

Licence No and Date	0311003102/09/04/2021
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.	24 / NC/3/MEET/Nov/202223/12
Case Status	Case Rejected
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003216AM23
RA File Number	03AA04033058 AM21
Licence No and Date	0311003205/21/04/2021
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.	25 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00002621AM23
RA File Number	30AA04004647 AM22
Licence No and Date	3011000736/12/06/2021
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: Percentage yield on molar basis for each step with supporting literature.	

Case No.	26 / NC/3/MEET/Nov/202223/12
Case Status	Case Rejected

Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003217AM23
RA File Number	03AA04028999 AM22
Licence No and Date	0311004821/22/06/2021
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.	27 / NC/3/MEET/Nov/202223/12
Case Status	Case Rejected
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003220AM23
RA File Number	03AA04044353 AM22
Licence No and Date	0311005322/12/07/2021
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.	28 / NC/3/MEET/Nov/202223/12
Case Status	Case Rejected
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003218AM23
RA File Number	03AA04066488 AM22
Licence No and Date	0311006599/01/09/2021
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.	29 / NC/3/MEET/Nov/202223/12
Case Status	Case Rejected
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM REVIW00003221AM23
RA File Number	03AA04066551 AM22
Licence No and Date	0311006600/01/09/2021
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.	30 / NC/3/MEET/Nov/202223/12										
Case Status	Case Approved										
Party Name	TITAN LABORATORIES PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022										
HQ File Number	HQRNORM REVIW00003191AM23										
RA File Number	03AX04001249 AM22										
Licence No and Date	0311011408/15/02/2022										
Norms Committee Decision:											
The Committee considered the request of firm for review of adhoc norms and taking cue from earlier decision for same export product / import item in Meeting No. 3/82-ALC4/2018 dated 05.06.2018 against advance authorization No. 0310815607 dated 07.09.2017 , it was decided to revise adhoc norms as under:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>ORLISTAT PELLETS 50 %</td><td>1 kg</td><td>1</td><td>ORLISTAT</td><td>0.505 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	ORLISTAT PELLETS 50 %	1 kg	1	ORLISTAT	0.505 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
ORLISTAT PELLETS 50 %	1 kg	1	ORLISTAT	0.505 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	31 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00381096AM22
RA File Number	34AX04000347 AM22
Licence No and Date	3411001937/09/03/2022
Norms Committee Decision:	
Deferred for comments of TE	

Case No.	32 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	GUPTA AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00381776AM22
RA File Number	05AX04001230 AM22
Licence No and Date	0511010862/10/03/2022
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. Indicate the chemical name of export and import item. ii. Chemistry of the reaction indicating calculation of requirement of raw materials, molecular weight, etc. with yield iii. Production / Consumption data duly certified by CA.	

Case No.	33 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	FDC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00381846AM22
RA File Number	03AX04001634 AM22
Licence No and Date	0311012524/10/03/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Apr/202223/1 dated 29/04/2022 against advance authorization	

No. **0311009325 dated 09.12.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
CHLORAMPHENICOL EYE DROPS 10 ML((EACH VIAL CONTAINS CHLORAMPHENICOL MICRONIZED 0.050GM NET WT OF BULK DRUG IS 20.85 KGS))	1 Vial	1	Chloramphenicol Micronized	51.00 mg / 10 ml Vial

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

Case No.	34 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SHIVA BIO CHEM INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00382075AM22
RA File Number	50AX04000031 AM22
Licence No and Date	5011000413/10/03/2022

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 COA of Export Product.**
- ii COA of Import item from foreign supplier.**
- iii Content of By-Products, its recovery and solvents.**
- iv Complete technical details, wastage claimed etc. as per Annexure to Appendix 4E.**

Case No.	35 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00382170AM22
RA File Number	34AX04000358 AM22

Licence No and Date	3411001942/10/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	36 / NC/3/MEET/Nov/202223/12				
Case Status	Case Approved				
Party Name	AUROBINDO PHARMA LTD				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022				
HQ File Number	HQRNORM APPLY 00383395AM22				
RA File Number	09AX04000280 AM22				
Licence No and Date	0911002654/11/03/2022				
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	Cefalexin Tablets 250mg(Cefalexin Tablets 250mg (Each film coated tablet contains Cefalexin Monohydrate Ph.Eur equivalent to anhydrous Cefalexin 250mg) [The relevant bulk drug in the export product is 75 Kgs])	1 Number	1	Cefalexin Monohydrate Ph Eur (Powder)	268.2 mg / 250 mg Tablet
2	Cefalexin Tablets 500mg(Cefalexin Tablets 500mg (Each film coated tablet contains Cefalexin Monohydrate Ph.Eur equivalent to anhydrous Cefalexin 500mg) [The relevant bulk drug in the export product is 2925 Kgs])	1 Number	1	Cefalexin Monohydrate Ph Eur (Powder)	536.4 mg / 500 mg Tablet
RA concerned may take further necessary action as per above decision of NC.					

Case No.	37 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AASHA BIOCHEM
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022

HQ File Number	HQRNORM APPLY 00383526AM22
RA File Number	10AX04000077 AM22
Licence No and Date	1011000943/11/03/2022
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) COA indicating moisture content of both export and impor (ii) Calculation with requirement of raw material for the manufacturing of export item giving justification for wastage.	

Case No.	38 / NC/3/MEET/Nov/202223/12													
Case Status	Case Approved													
Party Name	STERILE INDIA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022													
HQ File Number	HQRNORM APPLY 00383845AM22													
RA File Number	05AX04001021 AM22													
Licence No and Date	0511010960/11/03/2022													
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-ALC4/2020 dated 09.10.2020 against advance authorization No. 0510413470 dated 29.01.2020 , 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><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Ceftriaxone Sodium Sterile</td><td>1 kg</td><td>1</td><td>Ceftriaxone Sodium Non Sterile</td><td>1.04 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	Ceftriaxone Sodium Sterile	1 kg	1	Ceftriaxone Sodium Non Sterile	1.04 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Ceftriaxone Sodium Sterile	1 kg	1	Ceftriaxone Sodium Non Sterile	1.04 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	39 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	GLENMARK LIFE SCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00386066AM22			

RA File Number	03AX04001619 AM22			
Licence No and Date	0311012706/14/03/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhuc 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.
TELMISARTAN	1 kg	1	2N-PROPYL-4-METHYL-6-(1-METHYL-BENZIMIDAZOL-2-YL)BENZIMIDAZOLE	0.763 kg
		2	4-METHYL-2-BIPHENYL CARBOXYLIC ACID METHYL ESTER	0.60 kg
		3	METHANOL	3.69 kg
		4	METHYLENE CHLORIDE	2.20 kg
		5	ACETIC ACID GLACIAL	0.90 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	40 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00386506AM22
RA File Number	52AX04000090 AM22
Licence No and Date	5211002165/14/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	41 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022													
HQ File Number	HQRNORM APPLY 00386082AM22													
RA File Number	03AX04001667 AM22													
Licence No and Date	0311012710/14/03/2022													
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. 0311003273 dated 22.04.2021, 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>AZELAIC ACID GEL 15 percent (Pack Size 50 Grams) (Net Wt. of Azelaic Acid is 2250.00 Kgs.)</td> <td>300000 Numbers</td> <td>1</td> <td>Azelaic Acid</td> <td>2295.00 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.	AZELAIC ACID GEL 15 percent (Pack Size 50 Grams) (Net Wt. of Azelaic Acid is 2250.00 Kgs.)	300000 Numbers	1	Azelaic Acid	2295.00 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
AZELAIC ACID GEL 15 percent (Pack Size 50 Grams) (Net Wt. of Azelaic Acid is 2250.00 Kgs.)	300000 Numbers	1	Azelaic Acid	2295.00 kg										

Case No.	42 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	GUPTA AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00386306AM22
RA File Number	05AX04001267 AM22
Licence No and Date	0511010970/14/03/2022
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. Indicate the chemical name of export and import item. ii. Chemistry of the reaction indicating calculation of requirement of raw materials, molecular weight, etc. with yield iii. Production / Consumption data duly certified by CA..	

Case No.	43 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred

Party Name	PROEC ENERGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00386396AM22
RA File Number	05AX04001262 AM22
Licence No and Date	0511010975/14/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity. - COA and percentage composition of export indicating net content of each input in export.	

Case No.	44 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00386424AM22
RA File Number	03AX04001657 AM22
Licence No and Date	0311012790/14/03/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/May/202223/3 dated 27/05/2022 against advance authorization No. 0310814635 dated 14.07.2017 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

	Inflammatory And Antiseptic Lozenges Sugar Free and(all other flavours. Each lozenge contains (i) Benzydamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride- 1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 33.333 Kgs (ii) 14.778 Kgs (iii) 28733.356 Kgs.)	Number	2	Cetylpyridinium Chloride	1.356 gram
			3	Isomalt ST-M	2586 gram
2	Benzydamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg. Net content (i) 21.333 Kgs. (ii) 18389.439 Kgs.)	1000 Number	4	Benzydamine Hydrochloride	3.06 gram
			5	Isomalt ST-M	2586 gram
3	Benzydamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride-(3mg (ii) Isomalt ST-M - 2586mg. Net content (i) 12 Kgs. (ii) 10344 Kgs.)	1000 Number	6	Benzydamine Hydrochloride	3.06 gram
			7	Isomalt ST-M	2586 gram
4	Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 13.333 Kg (ii) 25924.878 Kg)	1000 Number	8	Cetylpyridinium Chloride	1.356 gram
			9	Isomalt ST-M	2586 gram
5	Cetylpyridinium Chloride And Benzydamine Hydrochloride Antiseptic Lozenges Sugar Free. Each lozenge contains(ii) Cetylpyridinium Chloride-1mg (ii) Isomalt ST-M - 2586mg. Net content (i) 5.22 Kg (ii) 13498.92 Kg)	1000 Number	9	Cetylpyridinium Chloride	1.02 gram
			10	Isomalt ST-M	2586 gram

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

Case No.	45 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AARTI INDUSTRIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00386427AM22
RA File Number	03AX04001504 AM22
Licence No and Date	0311012791/14/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	46 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00386436AM22
RA File Number	03AX04001649 AM22
Licence No and Date	0311012801/14/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	47 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00386056AM22
RA File Number	08AX04000650 AM22
Licence No and Date	0811004377/14/03/2022
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 COA of import item from foreign supplier showing Potency of Actual Import	

Case No.	48 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	HALDIA PETROCHEMICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00386453AM22
RA File Number	02AX04000187 AM22
Licence No and Date	0211002100/14/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to refer the case to Department of Chemical & Petrochemicals (D/o C&PC).	

Case No.	49 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00387157AM22
RA File Number	07AX04000477 AM22
Licence No and Date	0711003428/15/03/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	50 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	DPB ANTIBIOTICS
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00387310AM22
RA File Number	03AX04001617 AM22
Licence No and Date	0311012908/15/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. DML for export item. ii. Master Batch Formula. iii COA of import item from foreign supplier.	

Case No.	51 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	HALDIA PETROCHEMICALS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00389089AM22
RA File Number	02AX04000201 AM22
Licence No and Date	0211002113/16/03/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to refer the case to Department of Chemical & Petrochemicals (D/o C&PC).	

Case No.	52 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ANANTA MEDICARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00389497AM22
RA File Number	05AX04001229 AM22
Licence No and Date	0511011065/16/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	53 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00389551AM22			
RA File Number	05AX04001320 AM22			
Licence No and Date	0511011068/16/03/2022			
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:				

Dorzolamide Hydrochloride equivalent to Dorzolamide 20 mg (Equivalent to 2.600Kg of Bulk Drug), and Timolol Maleate equivalent to Timolol 5.0 mg (Equivalent to 0.650 Kg. of Bulk Drug))				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	54 / NC/3/MEET/Nov/202223/12																
Case Status	Case Approved																
Party Name	AARTI DRUGS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022																
HQ File Number	HQRNORM APPLY 00390668AM22																
RA File Number	03AX04001604 AM22																
Licence No and Date	0311013055/17/03/2022																
Norms Committee Decision:																	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/202223/8 dated 23.09.2022 against advance authorization No. 0311004037 dated 25.05.2021 , 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 items</td><td>Qty.</td></tr><tr><td rowspan="2">Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)</td><td rowspan="2">1 kg</td><td>1</td><td>Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate</td><td>1.240 kg</td></tr><tr><td>2</td><td>Piperazine Anhydrous</td><td>0.390 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg	2	Piperazine Anhydrous	0.390 kg
Export product	Qty.	Sl. No.	Import items	Qty.													
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg													
		2	Piperazine Anhydrous	0.390 kg													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	55 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	AARTI DRUGS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00390677AM22			

RA File Number	03AX04001595 AM22			
Licence No and Date	0311013059/17/03/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/202223/8 dated 23.09.2022 against advance authorization No. 0311004037 dated 25.05.2021, 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.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	56 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	AARTI DRUGS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00390678AM22			
RA File Number	03AX04001592 AM22			
Licence No and Date	0311013060/17/03/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/202223/8 dated 23.09.2022 against advance authorization No. 0311004037 dated 25.05.2021, 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.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg

		2	Piperazine Anhydrous	0.390 kg
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RA concerned may take further necessary action as per above decision of NC

Case No.	57 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00390743AM22
RA File Number	05AX04001256 AM22
Licence No and Date	0511011170/17/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **7/82-ALC4/2020 dated 04.12.2020** against advance authorization No. **0510415732 dated 03.11.2020**, 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.
CEFEPIME FOR INJECTION	1 kg	1	CEFEPIME HCL NON STERILE	0.655 kg

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

Case No.	58 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	HALDIA PETROCHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00390945AM22
RA File Number	02AX04000207 AM22
Licence No and Date	0211002128/17/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to refer the case to **Department of Chemical & Petrochemicals (D/o C&PC).**

Case No.	59 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00391117AM22
RA File Number	03AX04001728 AM22
Licence No and Date	0311013108/17/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/May/202223/3 dated 27/05/2022** against advance authorization No. **0310814635 dated 14.07.2017**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No	Import items	Qty.
1	Benzydamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and(all other flavours. Each lozenge contains (i) Benzydamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride- 1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 33.333 Kgs (ii) 14.778 Kgs (iii) 28733.356 Kgs.)	1000 Number	1.	Benzydamine Hydrochloride	3.06 gram
			2	Cetylpyridinium Chloride	1.356 gram
			3	Isomalt ST-M	2586 gram
2	Benzydamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg. Net content (i) 21.333 Kgs. (ii) 18389.439 Kgs.)	1000 Number	4	Benzydamine Hydrochloride	3.06 gram
			5	Isomalt ST-M	2586 gram
3	Benzydamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free. Each lozenge contains (i) Benzydamine Hydrochloride-(3mg (ii) Isomalt ST-M - 2586mg. Net content (i) 12 Kgs. (ii)	1000 Number	6	Benzydamine Hydrochloride	3.06 gram
			7	Isomalt ST-M	2586 gram

	10344 Kgs.)				
4	Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 13.333 Kg (ii) 25924.878 Kg)	1000 Number	8	Cetylpyridinium Chloride	1.356 gram
			9	Isomalt ST-M	2586 gram
5	Cetylpyridinium Chloride And Benzydamine Hydrochloride Antiseptic Lozenges Sugar Free. Each lozenge contains((i) Cetylpyridinium Chloride-1mg (ii) Isomalt ST-M - 2586mg. Net content (i) 5.22 Kg (ii) 13498.92 Kg)	1000 Number	9	Cetylpyridinium Chloride	1.02 gram
			10	Isomalt ST-M	2586 gram
RA concerned may take further necessary action as per above decision of NC.					

Case No.	60 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00390551AM22
RA File Number	03AX04001792 AM22
Licence No and Date	0311013033/17/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	61 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00390573AM22
RA File Number	03AX04001802 AM22
Licence No and Date	0311013041/17/03/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jan/202122/13 dated 21.01.2022** against advance authorization No. **0910068574 dated 13.03.2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
PROPYL PARABEN	1 kg	1	PARA HYDROXY BENZOIC ACID	0.80 kg
		2	N PROPANOL	0.347 kg

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

Case No.	62 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	MERIDIAN ENTERPRISES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00394323AM22
RA File Number	03AX04001862 AM22
Licence No and Date	0311013150/21/03/2022

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.
Dequalinium Chloride Oral Spray (Dequadin Oral Spray) 25 ML Bottle(Dequalinium Chloride Oral Spray (Dequadin Oral Spray) 25 ML Bottle. (Each ml contains: Dequalinium Chloride 0.5 percent (net content of Input per ml=5mg,Net content per 25ml bottle =125mg Total net content = 2.597 kgs))	1 Number	1	Dequalinium Chloride	127.50 mg

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

Case No.	63 / NC/3/MEET/Nov/202223/12
Case Status	Case Rejected
Party Name	ASOJ SOFT CAPS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00394911AM22
RA File Number	34AX04000397 AM22
Licence No and Date	3411001990/21/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the import item – Fish Lipid Oil (33:22) (For Product WELLOMEGA MAX) 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.	64 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	KRISHNA ANTIOXIDANTS PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00396339AM22			
RA File Number	03AX04001822 AM22			
Licence No and Date	0311013212/22/03/2022			
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. 3/82-ALC4/2019 dated 05.07.2019 against advance authorization No. 0310821359 dated 31.05.2018 , 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:				

		No.		
TRI ISODECYL PHOSPHITE	1 kg	1	YELLOW PHOSPHORUS	0.065 kg
		2	PHENOL	0.090 kg
		3	ISODECYL ALCOHOL	0.973 kg

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

Case No.	65 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00396819AM22
RA File Number	03AX04001590 AM22
Licence No and Date	0311013222/22/03/2022

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	Telmisartan and Amlodipine Tablets 40/10mg. Each uncoated tablets contains :(Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 10mg Net wt of Telmisartan Granules is 2020.800 Kgs Net wt of Amlodipine Besilate is 300.000 Kgs.)	1 Number	1	Amlodipine Besilate	10.20 mg
2	Telmisartan and Amlodipine Tablets 80/10mg. Each uncoated tablets contains :(Telmisartan 80 mg equivalent to Telmisartan granules 134.72mg Amlodipine Besilate equivalent to Amlodipine USP 10mg . Net wt of Telmisartan Granules is 10777.600 Kgs. Net wt of Amlodipine Besilate is 800.000 Kgs.)	1 Number	2	Amlodipine Besilate	10.20 mg

3	Telmisartan and Amlodipine Tablets 40/5mg. Each uncoated tablets contains :(Telmisartan 40 mg equivalent to Telmisartan granules 67.36mg Amlodipine Besilate equivalent to Amlodipine USP 5mg Net wt of Telmisartan Granules is 6286.933 Kgs. Net wt of Amlodipine Besilate is 466.667 Kgs.)	1 Number	3	Amlodipine Besilate	5.10 mg
4	Telmisartan and Amlodipine Tablets 80/5mg. Each uncoated tablets contains :(Telmisartan 80 mg equivalent to Telmisartan granules 134.72mg Amlodipine Besilate equivalent to Amlodipine USP 5mg Net wt of Telmisartan Granules is 10777.600 Kgs. Net wt of Amlodipine Besilate is 400.000 Kgs.)	1 Number	4	Amlodipine Besilate	5.10 mg

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

Case No.	66 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00398099AM22
RA File Number	09AX04000273 AM22
Licence No and Date	0911002734/23/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **13/82-ALC4/2018 dated 14/01/2019** against advance authorization No. **0910066244 dated 18.05.2018**, 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.
VALACYCLOVIR HYDROCHLORIDE MONOHYDRATE(SOLID)	1 kg	1	Carbobenzyloxy L valine CBZ L Valine	1.1824 kg
		2	N N DICYCLOHEXYL CARBODIIMIDE DCC	1.061 kg
		3	4 DIMETHYLAMINO PYRIDINE DMAP	0.028 kg
		4	ACYCLOVIR	0.758 kg

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

Case No.	67 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00398312AM22
RA File Number	03AX04001894 AM22
Licence No and Date	0311013248/23/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Apr/202223/1 dated 29.04.2022** against advance authorization No. **0311009262 dated 07.12.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Ramilich / Ramilich Comp / Ramipril HCT ZT/ZTV 5-12.5mg, (Net Wt. Hydrochlorothiazide 125.00 KGS)((Net Wt. Ramipril 50.00 KGS))	1 Number	1	Hydrochlorothiazide	12.75 mg / Tablet
			2	Ramipril	5.10 mg
2	Ramilich / Ramilich Comp / Ramipril HCT ZT/ZTV 2.5-12.5mg (Net Wt. Hydrochlorothiazide 125.00 KGS)((Net Wt. Ramipril 25.00 KGS))	1 Number	1	Hydrochlorothiazide	12.75 mg / Tablet
			2	Ramipril	2.55 mg
3	Ramilich / Ramilich Comp / Ramipril HCT ZT/ZTV 5-25mg (Net Wt. Hydrochlorothiazide 750.00 KGS)((Net Wt. Ramipril 150.00 KGS))	1 Number	1	Hydrochlorothiazide	25.50 mg / Tablet
			2	Ramipril	5.10 mg

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

Case No.	68 / NC/3/MEET/Nov/202223/12
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Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00398377AM22
RA File Number	03AX04001895 AM22
Licence No and Date	0311013250/23/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Dec/202122/12 dated 17.12.2021** against advance authorization No. **0311005566 dated 23.07.2021**, 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.
Bempedoic Acid and Ezetimibe Fixed Dose Combination Tablets Each Tablet content Bempedoic Acid 180mg and Ezetimibe 10mg)((Net content of Bempedoic Acid 2700kgs and Ezetimibe 150kgs in Total Export Qty) (AA for Free of cost material as per Para 4.11 of HBP & Para 4.19 of FTP & RBI Master Circular C-26 - Disallowing remittances for material being supplied free of cost)	1 Number	1	Bempedoic Acid	189.90 mg
		2	Ezetimibe	10.55 mg

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

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

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

Case No.	69 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022

HQ File Number	HQRNORM APPLY 00398576AM22										
RA File Number	05AX04001357 AM22										
Licence No and Date	0511011310/23/03/2022										
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Oct/202122/10 dated 12.11.2021 against advance authorization No. 0511000306 dated 21.12.2020, 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>Mydrimax Eye Drops 5ml Vial (Each ml Containing 8 mg Tropicamide)</td> <td>1 Vial</td> <td>1</td> <td>Tropicamide</td> <td>40.8 mg / 5 ml vial</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.	Mydrimax Eye Drops 5ml Vial (Each ml Containing 8 mg Tropicamide)	1 Vial	1	Tropicamide	40.8 mg / 5 ml vial
Export product	Qty.	Sl. No.	Import items	Qty.							
Mydrimax Eye Drops 5ml Vial (Each ml Containing 8 mg Tropicamide)	1 Vial	1	Tropicamide	40.8 mg / 5 ml vial							

Case No.	70 / NC/3/MEET/Nov/202223/12										
Case Status	Case Approved										
Party Name	SENTISS PHARMA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022										
HQ File Number	HQRNORM APPLY 00398579AM22										
RA File Number	05AX04001403 AM22										
Licence No and Date	0511011311/23/03/2022										
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Apr/202223/1 dated 29.04.2022 against advance authorization No. 0511003876 dated 28.07.2021, 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: <table border="1"> <thead> <tr> <th>Export product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import items</th> <th>Qty.</th> </tr> </thead> <tbody> <tr> <td>Inokain Eye Drops 0.4% 5ml</td> <td>1 Vial</td> <td>1</td> <td>Benoxinate HCL</td> <td>20.4 mg</td> </tr> </tbody> </table>		Export product	Qty.	Sl. No.	Import items	Qty.	Inokain Eye Drops 0.4% 5ml	1 Vial	1	Benoxinate HCL	20.4 mg
Export product	Qty.	Sl. No.	Import items	Qty.							
Inokain Eye Drops 0.4% 5ml	1 Vial	1	Benoxinate HCL	20.4 mg							

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

Case No.	71 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00400127AM22
RA File Number	05AX04001269 AM22
Licence No and Date	0511011349/24/03/2022

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/AM20 dated 02.08.2019** against advance authorization No. **0510398377 dated 04.05.2016**, 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.
Gemcitabine Hydrochloride(USP)	1 gram	1	2-Deoxy-2,-difluoro-D-ribofuranose-3,5-dibenzoate-1-methanesulphonate (T-8).	5.40 gram
		2	N-Acetyl Cytosine	2.92 gram

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

Case No.	72 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MATRIX LIFE SCIENCE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00401252AM22
RA File Number	03AX04001906 AM22
Licence No and Date	0311013320/25/03/2022

Norms Committee Decision:

Deferred for comments of TE.

Case No.	73 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00401410AM22
RA File Number	03AX04001856 AM22
Licence No and Date	0311013341/25/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/8 dated 23.09.2022** against advance authorization No. **0311004037 dated 25.05.2021**, 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.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg

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

Case No.	74 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	CIPLA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00401442AM22
RA File Number	03AX04001811 AM22
Licence No and Date	0311013347/25/03/2022

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-ALC4/2020 dated 09.10.2020** against advance authorization No. **0310836020 dated 27.04.2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as

applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Testosterone Topical Solution 30 / 1.5mg / ml Pack Size 110ml(Each Actuation delivers : Testosterone USP- 30mg Also contains Alcohol USP ?. Approx. 49.55% w/v (QS to 100% w/v))	50000 Numbers	1	Testosterone USP	96.39 kg
		2	Alcohol (Ethanol 95% v/v)	2725.00 kg

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

Case No.	75 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00401443AM22
RA File Number	03AX04001843 AM22
Licence No and Date	0311013348/25/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/8 dated 23.09.2022** against advance authorization No. **0311004037 dated 25.05.2021**, 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.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg

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

Case No.	76 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00401447AM22
RA File Number	03AX04001591 AM22
Licence No and Date	0311013350/25/03/2022

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.
AMBERCORE	1 kg	1	Ortho Tertiary Butyl Phenol	0.79 kg
		2	1,2 Epoxy butane	0.379 kg

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

Case No.	77 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	BIOXERA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00404711AM22
RA File Number	03AX04002017 AM22
Licence No and Date	0311013410/28/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Apr/202223/1 dated 29.04.2022** against advance authorization No. **0311009297 dated 08.12.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
BENFOTIAMINE	1 kg	1	VITAMIN B1	0.922 kg

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

Case No.	78 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00404330AM22
RA File Number	09AX04000308 AM22
Licence No and Date	0911002668/28/03/2022

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. **0911001814 dated 03.11.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
(2S,3S,5S)-2-amino-3-hydroxy-5-tert butyl carbonyl amino-1,6-diphenyl-hexane((2S,3S,5S)-2-amino-3-hydroxy-5-tert butyl carbonyl amino-1,6-diphenyl-hexane)	1 kg	1	(S,E)-5-AMINO-2-(DIBENZYLAMINO)-1,6-DIPHENYLHEX-4-EN-3-ONE	1.77 kg
		2	SODIUM BORO HYDRIDE	0.45 kg
		3	TETRA HYDRO FURAN	0.48 kg
		4	2,2,2 TRI FLUORO ACETIC ACID	2.16 kg
		5	DI TERT.BUTYL DI CARBONATE	0.92 kg

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

Case No.	79 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00404660AM22
RA File Number	03AX04001844 AM22
Licence No and Date	0311013405/28/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/8 dated 23.09.2022** against advance authorization No. **0311004037 dated 25.05.2021**, 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.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg

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

Case No.	80 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00404671AM22
RA File Number	34AX04000254 AM22
Licence No and Date	3411002035/28/03/2022

Norms Committee Decision:

Deferred for comments of TE.

Case No.	81 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MAHIMA LIFESCIENCES PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00405626AM22
RA File Number	05AX04001435 AM22
Licence No and Date	0511011420/29/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: Complete chemistry, molecular weight and percentage yield on molar basis as per Annexure to Appendix 4E.	

Case No.	82 / NC/3/MEET/Nov/202223/12				
Case Status	Case Approved				
Party Name	MAIVA PHARMA PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022				
HQ File Number	HQRNORM APPLY 00405985AM22				
RA File Number	07AX04000527 AM22				
Licence No and Date	0711003531/29/03/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jul/202122/4 dated 15.07.2021 against advance authorization No. 0711000657 dated 15.03.2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Furosemide Injection 10mg/mL - 2mL Vial(2mL Vial - filled with 20mg of furosemide as bulk drug mixed in water for injection and filled in 2mL Vial and capped with 13mm chlorobutyle Rubber Stopper)	270000 Numbers	1	Grey Westar RS SIL 1 (13mm Chlorobutyle Rubber Stopper Grey RFS)	Relevant as per packing policy
2	Furosemide Injection 10mg/mL - 4mL Vial(4mL Vial - filled with 40mg of furosemide as bulk drug mixed in water for injection and filled in 4mL Vial and capped with 13mm chlorobutyle Rubber Stopper)	450000 Numbers	1	Grey Westar RS SIL 1 (13mm Chlorobutyle Rubber Stopper Grey RFS)	Relevant as per packing policy

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

Case No.	83 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00406012AM22
RA File Number	05AX04001414 AM22
Licence No and Date	0511011438/29/03/2022
Norms Committee Decision: The firm vide e-mail dated 02.11.2022 has enclosed a copy of Surrender Letter dated 25.05.2022 issued by CLA, New Delhi. In view of above e-mail of firm, the Committee decided to withdraw the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	84 / NC/3/MEET/Nov/202223/12																
Case Status	Case Approved																
Party Name	COVALENT LABORATORIES PRIVATE LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022																
HQ File Number	HQRNORM APPLY 00408811AM22																
RA File Number	09AX04000089 AM22																
Licence No and Date	0911002806/30/03/2022																
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. 0910068464 dated 07.02.2020 , 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:																	
<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">Ceftriaxone Sodium Sterile (PKD 10 KG IN 20LTRS)(API)</td><td rowspan="2">1 kg</td><td>1</td><td>Ceftriaxone Sodium Non Sterile</td><td>1.04 kg</td></tr><tr><td>2</td><td>Acetone</td><td>1.72 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	Ceftriaxone Sodium Sterile (PKD 10 KG IN 20LTRS)(API)	1 kg	1	Ceftriaxone Sodium Non Sterile	1.04 kg	2	Acetone	1.72 kg
Export product	Qty.	Sl. No.	Import items	Qty.													
Ceftriaxone Sodium Sterile (PKD 10 KG IN 20LTRS)(API)	1 kg	1	Ceftriaxone Sodium Non Sterile	1.04 kg													
		2	Acetone	1.72 kg													

		3	Activated Carbon [Carbon Enoanticromos]	51.66 gram
		4	Aluminium Canisters 20L with inner & Outer Lids	Relevant as per packing policy with accountability

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

Case No.	85 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00408905AM22
RA File Number	34AX04000448 AM22
Licence No and Date	3411002052/30/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	86 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00408949AM22
RA File Number	52AX04000101 AM22
Licence No and Date	5211002273/30/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	87 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00407947AM22
RA File Number	09AX04000343 AM22
Licence No and	0911002789/30/03/2022

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Apr/202223/1 dated 29.04.2022 against advance authorization No. 0911002135 dated 22.12.2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Molnupiravir	1 kg	1	Cytidine	1.35 kg
		2	2,2-Dimethoxy Propane	3.00 kg
		3	DBU (1, 8-diazabicyclo [5.4.0] undec-7-ene	1.50 kg
		4	Isobutyric Anhydride	0.90 kg
		5	Isopropyl Alcohol (IPA)	2.00 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	88 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	GLENMARK PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00408086AM22			
RA File Number	03AX04002023 AM22			
Licence No and Date	0311013460/30/03/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jan/202122/13 dated 21.01.2022 against advance authorization No. 0311007209 dated 25.09.2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.

Colesevelam HCL for oral suspension 3.75 GM (Per Pack 30 Pouchs) (Total 5000 Packs)((Net. Content of Colesevelam Hydrochloride is 562.50 kgs))	5000 Packs	1	Colesevelam Hydrochloride	590.625 kg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	89 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	KRITI NUTRIENTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00408410AM22
RA File Number	56AX04000134 AM22
Licence No and Date	5611000874/30/03/2022
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 specification of import item with COA from foreign supplier. ii. Difference in specification of export and import item. iii Justification of wastage claimed.	

Case No.	90 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00408439AM22
RA File Number	05AX04001517 AM22
Licence No and Date	0511011486/30/03/2022
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 its comments.	

Case No.	91 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved

Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022																
HQ File Number	HQRNORM APPLY 00409415AM22																
RA File Number	31AX04000109 AM22																
Licence No and Date	3111001213/31/03/2022																
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 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="3">Para Benzoquinone (PBQ)</td><td rowspan="3">1 kg</td><td>1</td><td>Hydroquinone</td><td>1.07 kg</td></tr> <tr> <td>2</td><td>Sodium Chlorate</td><td>0.345 kg</td></tr> <tr> <td>3</td><td>MDC</td><td>0.25 kg</td></tr> </tbody> </table>		Export product	Qty.	Sl. No.	Import items	Qty.	Para Benzoquinone (PBQ)	1 kg	1	Hydroquinone	1.07 kg	2	Sodium Chlorate	0.345 kg	3	MDC	0.25 kg
Export product	Qty.	Sl. No.	Import items	Qty.													
Para Benzoquinone (PBQ)	1 kg	1	Hydroquinone	1.07 kg													
		2	Sodium Chlorate	0.345 kg													
		3	MDC	0.25 kg													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	92 / NC/3/MEET/Nov/202223/12										
Case Status	Case Approved										
Party Name	DEEPAK PHENOLICS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022										
HQ File Number	HQRNORM APPLY 00410198AM22										
RA File Number	34AX04000463 AM22										
Licence No and Date	3411002081/31/03/2022										
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 border="1"> <thead> <tr> <th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> <tr> <td>Phenol</td><td>6250 MT</td><td>1</td><td>Cumene</td><td>5279.126 MT</td></tr> </tbody> </table>		Export product	Qty.	Sl. No.	Import items	Qty.	Phenol	6250 MT	1	Cumene	5279.126 MT
Export product	Qty.	Sl. No.	Import items	Qty.							
Phenol	6250 MT	1	Cumene	5279.126 MT							

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

Case No.	93 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00409452AM22
RA File Number	34AX04000441 AM22
Licence No and Date	3411002060/31/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	94 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ORGANIC INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00410276AM22
RA File Number	06AX04000155 AM22
Licence No and Date	0611001257/31/03/2022
Norms Committee Decision:	
The Committee considered the case as per Agenda and it was observed that the Export Product appears to be food items, which is dealt in Norms Committee-6. Hence, it was decided to transfer the case to Norms Committee-6.	

Case No.	95 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00409480AM22
RA File Number	34AX04000458 AM22
Licence No and Date	3411002061/31/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	96 / NC/3/MEET/Nov/202223/12
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Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00409172AM22
RA File Number	03AX04002005 AM22
Licence No and Date	0311013493/31/03/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jul/202122/4 dated 15.07.2021** against advance authorization No. **0311002050 dated 03.03.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Rinza sip with Vitamin C (Flavours Orange/ Lemon/ Black Currant/ Other flavours) &(Rinza Sip (Flavours Orange/ Lemon/ Black currant/ Cranberry/ Honey Lemon/ Other flavours). Each sachet of 5gm contains Caffeine Anhydrous Powder 30mg. Net content of Caffeine Anhydrous Powder 23.64 Kgs.)	1 Number Sachet	1	Caffeine Anhydrous Powder	30.30 mg / 5 gm sachet
2	Rinza Tablets. Each tablet Contains Caffeine Anhydrous Powder 30 mg and Paracetamol BP 500 mg.(Net Content of Caffeine Anhydrous Powder - 169.76 Kgs and Paracetamol BP- 2829.27 Kgs.)	1 Number Tablet	2	Caffeine Anhydrous Powder	30.60 mg / 30 mg tablet
			3	Paracetamol BP	510 mg / 500 mg tablet
3	Rinza Sip for Children (Flavours Raspberry/ other flavours). Each sachet of 3gm contains Paracetamol BP - 280mg.(Net content- 96.15 Kgs.)	1 Number Sachet	4	Paracetamol BP	282.80 mg / 3 gm sachet

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

Case No.	97 / NC/3/MEET/Nov/202223/12
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Case Status	Case Approved													
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022													
HQ File Number	HQRNORM APPLY 00409618AM22													
RA File Number	31AX04000100 AM22													
Licence No and Date	3111001215/31/03/2022													
Norms Committee Decision: The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Mar/2022122/15 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 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">ETHYLENE DI AMINE (ORGANIC CHEMICAL)</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> </tbody> </table> RA concerned may take further necessary action as per above decision of NC		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
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										

Case No.	98 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00409264AM22
RA File Number	03AX04002067 AM22
Licence No and Date	0311013503/31/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: i. Stoichiometric balance between import and export on molar basis and yield to arrive at the quantity of raw material asked for. ii. If DMSO is used as a solvent, then recovery of same.	

iii. End use of export product.

Case No.	99 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00409628AM22
RA File Number	31AX04000110 AM22
Licence No and Date	3111001216/31/03/2022

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.
Veratrole (1,2, Dimethoxy Benzene)	1 kg	1	Phenol	0.749 kg
		2	Methanol	0.255 kg
		3	Hydrogen Peroxide (60%)	0.452 kg
		4	Acetone (Solvent)	0.078 kg
		5	Dimethyl Sulphate	0.502 kg
		6	Caustic Soda Lye	0.36 kg

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

Case No.	100 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00409265AM22
RA File Number	03AX04002070 AM22

Licence No and Date	0311013504/31/03/2022
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. Stoichiometric balance between import and export on molar basis and yield to arrive at the quantity of raw material asked for. iii. Recovery of solvent of DMSO & N-Heptane.	

Case No.	101 / NC/3/MEET/Nov/202223/12													
Case Status	Case Approved													
Party Name	STERILE INDIA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022													
HQ File Number	HQRNORM APPLY 00409822AM22													
RA File Number	05AX04001370 AM22													
Licence No and Date	0511011543/31/03/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jan/202021/4 dated 12.02.2021 against advance authorization No. 0510414007 dated 16.04.2020 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>VANCOMYCIN HYDROCHLORIDE (STERILE)</td><td>1 kg</td><td>1</td><td>Vancomycin HCL (Non Sterile)</td><td>1.01 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	VANCOMYCIN HYDROCHLORIDE (STERILE)	1 kg	1	Vancomycin HCL (Non Sterile)	1.01 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
VANCOMYCIN HYDROCHLORIDE (STERILE)	1 kg	1	Vancomycin HCL (Non Sterile)	1.01 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	102 / NC/3/MEET/Nov/202223/12			
Case Status	Case Deferred			
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00409266AM22			

RA File Number	03AX04002071 AM22
Licence No and Date	0311013505/31/03/2022
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. Stoichiometric Balance between import and export on molar basis, percentage yield at each stage to arrive at the quantity of raw material asked for. iii. Recovery of solvent Acetaldoxime.	

Case No.	103 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00410005AM22
RA File Number	09AX04000194 AM22
Licence No and Date	0911002814/31/03/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	104 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	NAVIN FLUORINE ADVANCED SCIENCES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00409269AM22			
RA File Number	03AX04002072 AM22			
Licence No and Date	0311013506/31/03/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Apr/202223/1 dated 29.04.2022 against advance authorization No. 0311005238 dated 09.07.2021, 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:				

8-Chloro-6-(Trifluoromethyl imidazo 1,2-a]pyridine-2-carboxylic acid (QEK31)	1 kg	1	2-Amino-3-chloro-5-(TFM) Pyridine	1.035 kg
		2	Ethyl Pyruvate	0.676 kg
		3	Bromine	1.143 kg
		4	Dichloromethane	Not allowed, as it is being reused
		5	Acetic acid	Not allowed, as it is being reused

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

Case No.	105 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00410013AM22
RA File Number	09AX04000193 AM22
Licence No and Date	0911002816/31/03/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	106 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000024AM23
RA File Number	09AX04000398 AM22
Licence No and Date	0911002823/01/04/2022
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. NC/3/MEET/Mar/202122/16 dated 08/04/2022 against advance authorization No.	

0911001871 dated 17/11/2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

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

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

Case No.	107 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	SHIVAM ADDITIVES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000032AM23
RA File Number	13AX04000126 AM22
Licence No and Date	1311001135/01/04/2022

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. **1311000341 dated 19-05-2021**, 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.
AZODICARBONAMIDE (BLOWING AGENT), PURITY MINIMUM 99.50 PERCENT, PARTICLE SIZE 4.5 TO 5.5 PERCENT MICRON	200000 kg	1	AZODICARBONAMIDE CRUDE PURITY MINIMUM 97 PERCENT PARTICLE SIZE 13 TO 15 PERCENT MICRON	201000 kg

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

Case No.	108 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022				
HQ File Number	HQRNORM APPLY 00000041AM23				
RA File Number	07AX04000598 AM22				
Licence No and Date	0711003587/03/04/2022				
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 Injection USP 90mg per 10mL Vial.(10mL Vial - filled with 90mg of Sodium Chloride as bulk drug filled in 10mL Vial and capped with 13mm Grey Serum ChlorobutyI Rubber Stopper)	642375 Numbers	1	13mm GreySerum ChlorobutyI R/S-RFS-C14226422GS6TP3	Relevant as per Packing Policy
2	Sterile Water for Injection 10mL Vial(Sterile Water for injection, filled in 10mL Vial and capped with 13mm Grey Serum ChlorobutyI Rubber Stopper)	900000 Numbers	2	13mm GreySerum ChlorobutyI R/S-RFS-C14226422GS6TP3	Relevant as per Packing Policy
RA concerned may take further necessary action as per above decision of NC.					

Case No.	109 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000042AM23
RA File Number	07AX04000596 AM22
Licence No and Date	0711003588/03/04/2022
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 Injection USP 90mg per 10mL Vial.(10mL Vial - filled with 90mg of Sodium Chloride as bulk drug filled in 10mL Vial and capped with 13mm GreySerum ChlorobutyI Rubber Stopper)	360000 Numbers	1	13mm GreySerum ChlorobutyI R/S-RFS-C14226422GS6TP3	Relevant as per Packing Policy
2	Sterile Water for Injection 10mL Vial(Sterile Water for injection, filled in 10mL Vial and capped with 13mm GreySerum ChlorobutyI Rubber Stopper)	668250 Numbers	2	13mm GreySerum ChlorobutyI R/S-RFS-C14226422GS6TP3	Relevant as per Packing Policy

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

Case No.	110 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000054AM23
RA File Number	07AX04000570 AM22
Licence No and Date	0711003549/04/04/2022

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.
Valproate Sodium Injection 100mg/mL, 5ml(5mL Vial - filled with 20mg of Valporate Sodium as bulk drug is filled in 5mL Vial and capped with 20mm chlorobutyle Rubber Stopper)	270000 Numbers	1	WPS S10-F451 4432/50G B2-40 WESTARRS1m/PK (20mm Chlorobutyle Rubber Stopper)	Relevant as per Packing Policy

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

Case No.	111 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	RUMIT LIFE CARE
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000057AM23
RA File Number	03AX04001875 AM22
Licence No and Date	0311013605/04/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Jul/202122/4 dated 15.07.2021** against advance authorization No. **0311001996 dated 08.03.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Betamethasone Dipropionate IP/BP/EP/USP	115 kg	1	Betamethasone IP/BP/EP/USP	99.82 kg

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

Case No.	112 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000058AM23
RA File Number	03AX04002119 AM22
Licence No and Date	0311013606/04/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09/09/2022** against advance authorization No. **0311010684 dated 19/01/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
DI ISODECYL PHENYL PHOSPHITE((DDPP))	1 kg	1	PHENOL	0.238 kg
		2	ISODECYL ALCOHOL OR 2 PROPYL HEPTANOL	0.734 kg
		3	YELLOW PHOSPHORUS	0.075 kg

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

Case No.	113 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	PIRAMAL PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000061AM23
RA File Number	03AX04002100 AM22
Licence No and Date	0311013612/05/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/8 dated 23/09/2022** against advance authorization No. **0311002962 dated 31/03/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty.
1	Atorvastatin Calcium Tablets USP 10mg((Pack Size 90 tabs) Tablet (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	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	250cc Rnd White 53/400 Hdpe Sclair 58a (Plastic Bottles 250CC white HDPE Round 38mm)	Relevant as per packing policy
3	Atorvastatin Calcium Tablets USP 20mg((Pack Size 90 tabs) (Net wt. of Import Sr. No. 1 is 148.784kgs, Sr. No. 2 is 826.929kg, Sr. No. 3 is 234.698kg, Sr. No. 5 is 75750 Nos.))	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	22.830 mg
			2	Microcrystalline Cellulose (MCC) NF (Avicel PH 102)	129.427 mg
			3	Calcium Acetate	36.090 mg
			4	Plastic Bottles 75CC white HDPE Round 38mm	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	Plastic Bottles 75CC white HDPE Round 38mm	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	1 Number Tablet	1	Atorvastatin Calcium Propylene Glycol Solvate USP	45.595 mg
			2	Microcrystalline Cellulose (MCC)	258.08 mg

	11383.205kg, Sr. No. 3 is 3232.444kg, Sr. No. 5 is 47086 Nos.))			NF (Avicel PH 102)	
			3	Calcium Acetate	71.963 mg
			4	Plastic Bottles 120CC white HDPE Round 38mm	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	1500cc Round Extrusion 89/400 Neck White (Plastic Bottles 1500CC white HDPE Round 38mm)	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	1500cc Round Extrusion 89/400 Neck White (Plastic Bottles 1500CC white HDPE Round 38mm)	Relevant as per packing policy
Note: The above norms are valid only for subject to fulfillment of following conditions:					
1. Export Product being Patented Medicine, be filed with USFDA filing ANDA (A New Drug Application) of Apotex Corp, US. Agent for Apotex Inc., Candada.					
2. Export to USA only.					
3. Firm holding Certificate of Manufacturing Exclusivity.					
RA concerned may take further necessary action as per above decision of NC.					

Case No.	114 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000064AM23
RA File Number	09AX04000330 AM22
Licence No and Date	0911002827/05/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	115 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000066AM23
RA File Number	03AX04001985 AM22
Licence No and Date	0311013625/05/04/2022

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.
CILOSTAZOL	1 kg	1	5-(4-CHLOROBUTYL)-1-CYCLOHEXYL 1H TETRAZOLE	0.85 kg
		2	6-HYDROXY-2 OXO-1,2,3,4-TETRAHYDROQUINOLINE	0.59 kg
		3	METHANOL	4.00 kg
		4	TOLUENE	0.30 kg
		5	TRICAPRLY METHYL AMMONIUM CHLORIDE	0.100 kg

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

Case No.	116 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000086AM23
RA File Number	07AX04000582 AM22
Licence No and Date	0711003633/06/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	117 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000087AM23
RA File Number	07AX04000581 AM22
Licence No and Date	0711003634/06/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	118 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	KAIRAV CHEMOFARBE INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00000101AM23			
RA File Number	03AX04002054 AM22			
Licence No and Date	0311013691/07/04/2022			
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. 03110011707 dated 23.02.2022 , 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:				

ACETONITRILE (Purity Min. 99.9%, Moisture less than 500 PPM)	350 MT	1	ACETONITRILE – LOW PURITY (Purity 98%)	416.51 MT
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RA concerned may take further necessary action as per above decision of NC.

Case No.	119 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000106AM23
RA File Number	03AX04000074 AM23
Licence No and Date	0311013696/07/04/2022

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. **0311003205 dated 21.04.2021**, 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.
AMANTADINE HYDROCHLORIDE 100 MG CAPSULES	1350000 Numbers	1	AMANTADINE HYDROCHLORIDE CEP Ph EUR RA001136	137.70 kg

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

Case No.	120 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000109AM23
RA File Number	09AX04000400 AM22
Licence No and Date	0911002840/07/04/2022

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. **0911001871 dated 17/11/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

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

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

Case No.	121 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000139AM23
RA File Number	08AX04000776 AM22
Licence No and Date	0811004611/08/04/2022

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	DEXAMETHASONE TABLETS USP 0.5 MG((ACTIVE INGREDIENT: DEXAMETHASONE USP - NET WT. 4.693 KGS.))	1 Number Tablet	1	DEXAMETHASONE USP	0.510 mg
			2	CORN STARCH NF	6.75 mg
			3	LACTOSE MONOHYDRATE NF/PH.EUR	39.485 mg
			4	SUCROSE NF	2.50 mg
			5	MAGNESIUM STEARATE PH.EUR/NF	0.77 mg

2	DEXAMETHASONE TABLETS USP 0.75 MG((ACTIVE INGREDIENT: DEXAMETHASONE USP - NET WT. 4.318 KGS.))	1 Number Tablet	1	DEXAMETHASONE USP	0.765 mg
			2	CORN STARCH NF	10.125 mg
			3	LACTOSE MONOHYDRATE NF/PH.EUR	58.303 mg
			4	SUCROSE NF	3.70 mg
			5	MAGNESIUM STEARATE PH.EUR/NF	1.12 mg
3	DEXAMETHASONE TABLETS USP 1 MG((ACTIVE INGREDIENT: DEXAMETHASONE USP - NET WT. 14.010 KGS.))	1 Number Tablet	1	DEXAMETHASONE USP	1.02 mg
			2	CORN STARCH NF	13.50 mg
			3	LACTOSE MONOHYDRATE NF/PH.EUR	78.970 mg
			4	SUCROSE NF	5.00 mg
			5	MAGNESIUM STEARATE PH.EUR/NF	1.50 mg
4	DEXAMETHASONE TABLETS USP 1.5 MG((ACTIVE INGREDIENT: DEXAMETHASONE USP - NET WT. 3.630 KGS.))	1 Number Tablet	1	DEXAMETHASONE USP	1.53 mg
			2	CORN STARCH NF	13.50 mg
			3	LACTOSE MONOHYDRATE NF/PH.EUR	78.476 mg
			4	SUCROSE NF	5.00 mg
			5	MAGNESIUM STEARATE PH.EUR/NF	1.50 mg
5	DEXAMETHASONE TABLETS USP 2 MG((ACTIVE INGREDIENT: DEXAMETHASONE USP - NET WT. 79.013 KGS.))	1 Number Tablet	1	DEXAMETHASONE USP	2.04 mg
			2	CORN STARCH NF	13.50 mg
			3	LACTOSE MONOHYDRATE	78.00 mg

				NF/PH.EUR	
			4	SUCROSE NF	5.00 mg
			5	MAGNESIUM STEARATE PH.EUR/NF	1.50 mg
6	DEXAMETHASONE TABLETS USP 4 MG((ACTIVE INGREDIENT: DEXAMETHASONE USP - NET WT. 301.008 KGS.))	1 Number Tablet	1	DEXAMETHASONE USP	4.08 mg
			2	CORN STARCH NF	13.50 mg
			3	LACTOSE MONOHYDRATE NF/PH.EUR	75.985 mg
			4	SUCROSE NF	5.00 mg
			5	MAGNESIUM STEARATE PH.EUR/NF	1.50 mg
7	DEXAMETHASONE TABLETS USP 6 MG((ACTIVE INGREDIENT: DEXAMETHASONE USP - NET WT. 101.983 KGS.))	1 Number Tablet	1	DEXAMETHASONE USP	6.12 mg
			2	CORN STARCH NF	13.50 mg
			3	LACTOSE MONOHYDRATE NF/PH.EUR	73.99 mg
			4	SUCROSE NF	5.00 mg
			5	MAGNESIUM STEARATE PH.EUR/NF	1.50 mg
RA concerned may take further necessary action as per above decision of NC.					

Case No.	122 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	KusuMa PharMa
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000150AM23
RA File Number	03AX04000018 AM23

Licence No and Date	0311013747/08/04/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis. Details of indigenous input with quantity.	

Case No.	123 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000151AM23
RA File Number	09AX04000402 AM22
Licence No and Date	0911002848/08/04/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	124 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000158AM23
RA File Number	03AX04000111 AM23
Licence No and Date	0311013749/10/04/2022
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/May/202223/4 dated 17/06/2022 against advance authorization No. 0311004509 dated 10/06/2021, 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.
DINONYLATED DIPHENYLAMINE (YALUB DND)	1 kg	1	DIPHENYLAMINE	0.4134 kg
		2	NONENE	0.4 kg
		3	ACTIVATED CLAY	0.05 kg

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

Case No.	125 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000159AM23
RA File Number	03AX04000094 AM23
Licence No and Date	0311013750/10/04/2022

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/May/202223/4 dated 17/06/2022** against advance authorization No. **0311004509 dated 10/06/2021**, 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.
DINONYLATED DIPHENYLAMINE (YALUB DND)	1 kg	1	DIPHENYLAMINE	0.4134 kg
		2	NONENE	0.4 kg
		3	ACTIVATED CLAY	0.05 kg

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

Case No.	126 / NC/3/MEET/Nov/202223/12
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Case Status	Case Approved
Party Name	SANDHYA ORGANIC CHEMICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000161AM23
RA File Number	03AX04000062 AM23
Licence No and Date	0311013759/11/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09/09/2022** against advance authorization No. **0311010684 dated 19/01/2022**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
DIPHENYL ISODECYL PHOSPHITE((DPDP))	1 kg	1	PHENOL	0.238 kg
		2	ISODECYL ALCOHOL OR 2 PROPYL HEPTANOL	0.734 kg
		3	YELLOW PHOSPHORUS	0.075 kg

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

Case No.	127 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000168AM23
RA File Number	03AX04000080 AM23
Licence No and Date	0311013777/11/04/2022

Norms Committee Decision:

Deferred for comments of TE.

Case No.	128 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved

Party Name	AARTI DRUGS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022																
HQ File Number	HQRNORM APPLY 00000169AM23																
RA File Number	03AX04000017 AM23																
Licence No and Date	0311013787/11/04/2022																
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/202223/8 dated 23.09.2022 against advance authorization No. 0311004037 dated 25.05.2021, 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 rowspan="2">Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)</td> <td rowspan="2">1 kg</td> <td>1</td> <td>Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate</td> <td>1.240 kg</td> </tr> <tr> <td>2</td> <td>Piperazine Anhydrous</td> <td>0.390 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.	Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg	2	Piperazine Anhydrous	0.390 kg
Export product	Qty.	Sl. No.	Import items	Qty.													
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg													
		2	Piperazine Anhydrous	0.390 kg													

Case No.	129 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SUNSHIELD CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000186AM23
RA File Number	03AX04000112 AM23
Licence No and Date	0311013797/11/04/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products.	

- iv. **Stoichiometric balance between import and export on molar basis.**
v. **Details of indigenous input with quantity.**

Case No.	130 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ENVEE DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000202AM23
RA File Number	34AX04000001 AM23
Licence No and Date	3411002110/12/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	131 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	AHLCON PARENTERALS (INDIA) LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000211AM23
RA File Number	05AX04001545 AM22
Licence No and Date	0511011860/12/04/2022

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.
SODIUM CHLORIDE INTRAVENOUS INFUSION 0.9% 1000ML (SODIUM CHLORIDE INTRAVENOUS INFUSION 0.9% 1000ML (Empty bottle weight - 39 Grms, Filled bottle weight of Sodium Chloride - 1082 grams))	1 kg	1	PURELL PE 3220D (LDPE Granule)	1.05 kg /kg content in the export product
		2	4903 TPE 8558/45A TRIM TEC CAP PLASTIC CAP	Relevant as per packing policy

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

Case No.	132 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ARENE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000197AM23
RA File Number	09AX04000016 AM23
Licence No and Date	0911002850/12/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	133 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000199AM23
RA File Number	09AX04000304 AM22
Licence No and Date	0911002851/12/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	134 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000220AM23
RA File Number	08AX04000742 AM22
Licence No and Date	0811004640/13/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	135 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022

and Date				
HQ File Number	HQRNORM APPLY 00000248AM23			
RA File Number	03AX04000163 AM23			
Licence No and Date	0311013879/17/04/2022			
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/May/202223/4 dated 17/06/2022 against advance authorization No. 0311004509 dated 10/06/2021, 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.
DINONYLATED DIPHENYLAMINE (YALUB DND)	1 kg	1	DIPHENYLAMINE	0.4134 kg
		2	NONENE	0.4 kg
		3	ACTIVATED CLAY	0.05 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	136 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000274AM23
RA File Number	30AX04000006 AM23
Licence No and Date	3011002023/18/04/2022
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, molecular weight and percentage yield on molar basis may be furnished in line with Annexure to Appendix 4E.	

Case No.	137 / NC/3/MEET/Nov/202223/12
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Case Status	Case Deferred
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000256AM23
RA File Number	09AX04000404 AM22
Licence No and Date	0911002859/18/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	138 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ANUH PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000257AM23
RA File Number	03AX04001828 AM22
Licence No and Date	0311013920/18/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	139 / NC/3/MEET/Nov/202223/12										
Case Status	Case Approved										
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022										
HQ File Number	HQRNORM APPLY 00000260AM23										
RA File Number	03AX04000065 AM23										
Licence No and Date	0311013922/18/04/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Apr/202223/1 dated 29/04/2022 against advance authorization No. 0310796757 dated 23/06/2015 , 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>AZITHROMYCIN DIHYDRATE</td><td>1 kg</td><td>1</td><td>AZITHROMYCIN AMINE</td><td>1.04 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import items	Qty.	AZITHROMYCIN DIHYDRATE	1 kg	1	AZITHROMYCIN AMINE	1.04 kg
Export Product	Qty.	Sl. No.	Import items	Qty.							
AZITHROMYCIN DIHYDRATE	1 kg	1	AZITHROMYCIN AMINE	1.04 kg							

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

Case No.	140 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	NEXUS PHARMA CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000267AM23
RA File Number	08AX04000024 AM23
Licence No and Date	0811004699/18/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Oct/202223/11 dated 31/10/2022** against advance authorization No. **0811003272 dated 01.12.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Clobetasol Propionate USP	1 kg	1	Betamethasone base	1.00 kg

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

Case No.	141 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MITHILA RASAYAN PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000290AM23
RA File Number	03AX04000086 AM23
Licence No and Date	0311013960/19/04/2022

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. **Percentage of Zinc Diacrylate in Export Product.**
 ii. **How the export is modified.**
 iii. **The name of Modifying Agent and its content in export.**

Case No.	142 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AMANTA HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000291AM23
RA File Number	08AX04000760 AM22
Licence No and Date	0811004729/19/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	143 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SUVEN PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000293AM23
RA File Number	09AX04000008 AM23
Licence No and Date	0911002860/19/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	144 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	DELTA FINOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000298AM23
RA File Number	03AX04002053 AM22
Licence No and Date	0311013980/19/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	145 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved

Party Name	HETERO DRUGS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022													
HQ File Number	HQRNORM APPLY 00000299AM23													
RA File Number	09AX04000007 AM23													
Licence No and Date	0911002862/19/04/2022													
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. 6/82-ALC4/2018 dated 26.07.2018 against advance authorization No. 0910065042 dated 15.05.2017, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: <table 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>APREPITANT</td> <td>1 kg</td> <td>1</td> <td>(1R)-1[3,5 BIS (TRIFLUOROMETHYL) PHENYL(2r,3s)-3-(4-fluoro phenyl) morpholinyl ether,p-toluene sulphonic acid salt</td> <td>2.10 kg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC					Export Product	Qty.	Sl. No.	Import items	Qty.	APREPITANT	1 kg	1	(1R)-1[3,5 BIS (TRIFLUOROMETHYL) PHENYL(2r,3s)-3-(4-fluoro phenyl) morpholinyl ether,p-toluene sulphonic acid salt	2.10 kg
Export Product	Qty.	Sl. No.	Import items	Qty.										
APREPITANT	1 kg	1	(1R)-1[3,5 BIS (TRIFLUOROMETHYL) PHENYL(2r,3s)-3-(4-fluoro phenyl) morpholinyl ether,p-toluene sulphonic acid salt	2.10 kg										

Case No.	146 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	RAVOO'S LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000343AM23
RA File Number	09AX04000225 AM22
Licence No and Date	0911002468/20/04/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	147 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AVID ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000351AM23
RA File Number	34AX04000065 AM23

Licence No and Date	3411002146/20/04/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information /documents from the firm: Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.	

Case No.	148 / NC/3/MEET/Nov/202223/12																
Case Status	Case Approved																
Party Name	INDIA GLYCOLS LIMITED																
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022																
HQ File Number	HQRNORM APPLY 00000352AM23																
RA File Number	05AX04000147 AM23																
Licence No and Date	0511011991/20/04/2022																
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. NC/3/MEET/Sep202223/8 dated 23.09.2022 against advance authorization No. 0511005996 dated 08.11.2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:																	
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="3">Mono Ethylene Glycol (MEG)</td><td rowspan="3">1 kg</td><td>1</td><td>Denatured Ethyl Alcohol</td><td>1.123 kg</td></tr><tr><td>2</td><td>Silver Catalyst (Activity 17% to 18%)</td><td>0.000228 kg</td></tr><tr><td>3</td><td>Alumina Catalyst</td><td>0.000362 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Mono Ethylene Glycol (MEG)	1 kg	1	Denatured Ethyl Alcohol	1.123 kg	2	Silver Catalyst (Activity 17% to 18%)	0.000228 kg	3	Alumina Catalyst	0.000362 kg
Export product	Qty.	Sl. No.	Import items	Qty.													
Mono Ethylene Glycol (MEG)	1 kg	1	Denatured Ethyl Alcohol	1.123 kg													
		2	Silver Catalyst (Activity 17% to 18%)	0.000228 kg													
		3	Alumina Catalyst	0.000362 kg													
RA concerned may take further necessary action as per above decision of NC.																	

Case No.	149 / NC/3/MEET/Nov/202223/12
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Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000333AM23
RA File Number	07AX04000044 AM23
Licence No and Date	0711003752/20/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	150 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000337AM23
RA File Number	03AX04000169 AM23
Licence No and Date	0311014011/20/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	151 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	HONOUR LAB LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000361AM23
RA File Number	09AX04000399 AM22
Licence No and Date	0911002884/21/04/2022
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:	

METHOXY-6-(METHOXYCARBONYL)-4-OXO		2	Methyl-4-Methoxy Acetoacetate	0.725 kg
		3	Di Methyl Oxalate	1.17 kg
		4	Lithium Hydroxide	0.300 kg

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

Case No.	152 / NC/3/MEET/Nov/202223/12										
Case Status	Case Approved										
Party Name	BIOXERA PHARMA PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022										
HQ File Number	HQRNORM APPLY 00000365AM23										
RA File Number	03AX04000297 AM23										
Licence No and Date	0311014046/21/04/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Apr/202223/1 dated 29.04.2022 against advance authorization No. 0311009297 dated 08.12.2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>BENFOTIAMINE</td><td>1 kg</td><td>1</td><td>VITAMIN B1</td><td>0.922 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	BENFOTIAMINE	1 kg	1	VITAMIN B1	0.922 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
BENFOTIAMINE	1 kg	1	VITAMIN B1	0.922 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	153 / NC/3/MEET/Nov/202223/12			
Case Status	Case Deferred			
Party Name	ZYTEX BIOTECH PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00000381AM23			
RA File Number	03AX04000342 AM23			
Licence No and	0311014101/22/04/2022			

Date	
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 its comments.	

Case No.	154 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000369AM23
RA File Number	03AX04000145 AM23
Licence No and Date	0311014065/22/04/2022

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.
AMIODARONE HCL	1 kg	1	2-Butyl-3-(3,5-Diiodo-4-Hydroxy Benzoyl)	0.9135 kg
		2	Toluene	2.70 kg

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

Case No.	155 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000370AM23
RA File Number	03AX04000191 AM23
Licence No and Date	0311014067/22/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/8 dated 23.09.2022** against advance authorization No. **0311004037 dated 25.05.2021**, 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.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg

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

Case No.	156 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000374AM23
RA File Number	03AX04000319 AM23
Licence No and Date	0311014080/22/04/2022
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. Difference between YAPOX CL 30/10 (for which norms have already been fixed) and current Export Product YAPOX LM 30/10, since chemical name remains same.	

Case No.	157 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000389AM23
RA File Number	08AX04000767 AM22
Licence No and Date	0811004766/23/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	158 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000391AM23
RA File Number	03AX04000196 AM23
Licence No and Date	0311014132/25/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/8 dated 23.09.2022** against advance authorization No. **0311004037 dated 25.05.2021**, 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.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg

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

Case No.	159 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	BIOXERA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000400AM23
RA File Number	03AX04000344 AM23
Licence No and Date	0311014146/25/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Apr/202223/1 dated 29.04.2022** against advance authorization No. **0311009297 dated 08.12.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
BENFOTIAMINE	1 kg	1	VITAMIN B1	0.922 kg

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

Case No.	160 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000403AM23
RA File Number	31AX04000003 AM23
Licence No and Date	3111001301/25/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	161 / NC/3/MEET/Nov/202223/12										
Case Status	Case Approved										
Party Name	BIOLOGICAL E. LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022										
HQ File Number	HQRNORM APPLY 00000425AM23										
RA File Number	09AX04000026 AM23										
Licence No and Date	0911002902/26/04/2022										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/202223/8 dated 23.09.2022 against advance authorization No. 0210207903 dated 24.10.2017 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:											
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>NOSCAPINE USP/BP/Ph.Eur/JP</td><td>1 kg</td><td>1</td><td>NOSCAPINE CRUDE 95 PERCENT</td><td>1.15 kg</td></tr></table>		Export Product	Qty.	Sl. No.	Import items	Qty.	NOSCAPINE USP/BP/Ph.Eur/JP	1 kg	1	NOSCAPINE CRUDE 95 PERCENT	1.15 kg
Export Product	Qty.	Sl. No.	Import items	Qty.							
NOSCAPINE USP/BP/Ph.Eur/JP	1 kg	1	NOSCAPINE CRUDE 95 PERCENT	1.15 kg							

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

Case No.	162 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000432AM23
RA File Number	09AX04000029 AM23
Licence No and Date	0911002905/26/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	163 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000436AM23
RA File Number	03AX04000252 AM23
Licence No and Date	0311014187/26/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Apr/202223/1 dated 29.04.2022** against advance authorization No. **0310796757 dated 23.06.2015**, 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.
AZITHROMYCIN DIHYDRATE	1 kg	1	AZITHROMYCIN AMINE	1.04 kg

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

Case No.	164 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022

and Date	
HQ File Number	HQRNORM APPLY 00000438AM23
RA File Number	03AX04001990 AM22
Licence No and Date	0311014190/26/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	165 / NC/3/MEET/Nov/202223/12													
Case Status	Case Approved													
Party Name	MICRO LABS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022													
HQ File Number	HQRNORM APPLY 00000410AM23													
RA File Number	07AX04000034 AM23													
Licence No and Date	0711003861/26/04/2022													
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. NC/3/MEET/Sep/202223/9 dated 07.10.2022 against advance authorization No. 0711003323 dated 02.03.2022 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML BP/EP/USP/IP 323.80 KG)</td><td>1 Number</td><td>1</td><td>TRANEXAMIC ACID</td><td>1100 mg / 10 ml Vial</td></tr></table>					Export Product	Qty.	Sl. No.	Import items	Qty.	TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML BP/EP/USP/IP 323.80 KG)	1 Number	1	TRANEXAMIC ACID	1100 mg / 10 ml Vial
Export Product	Qty.	Sl. No.	Import items	Qty.										
TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML TRANEXAMIC ACID INJECTION SOLUTION 1000MG/10ML BP/EP/USP/IP 323.80 KG)	1 Number	1	TRANEXAMIC ACID	1100 mg / 10 ml Vial										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	166 / NC/3/MEET/Nov/202223/12			
Case Status	Case Deferred			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00000411AM23			

RA File Number	07AX04000019 AM23
Licence No and Date	0711003862/26/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	167 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000412AM23
RA File Number	07AX04000610 AM22
Licence No and Date	0711003606/26/04/2022

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	Bumetanide Inj USP 1mg / 4mL(Bumetanide Injection 0.25mg/mL, 4mL vial - 1mg of bulk drug filled in 4mL vial and capped with 13mm Rubber Stopper & 13mm Green colour Matte finish Seals)	91800 Numbers	1	13FO LQ 3768 GREEN MATTE TOP (13mm Green Color Matte Finish Flip Off Seals)	Relevant as per Packing Policy
2	Bumetanide Inj USP 1mg /10mL (Bumetanide Injection 0.25mg/mL, 10mL vial - 2.5mg of bulk drug filled in 10mL vial and capped with 13mm Rubber Stopper & 13mm Green colour Matte finish Seals)	91800 Numbers	2	13FO LQ 3768 GREEN MATTE TOP (13mm Green Color Matte Finish Flip Off Seals)	Relevant as per Packing Policy
3	Phenytoin Sodium Inj USP100mg /2mL ("Phenytoin Sodium Injection USP 50mg/mL - 100mg of Phenytoin Sodium as bulk drug filled in 2mL Vial and capped with 13mm Rubber Stopper & 13mm Green colour Matte finish Seals")	91800 Numbers	3	13FO LQ 3768 GREEN MATTE TOP (13mm Green Color Matte Finish Flip Off Seals)	Relevant as per Packing Policy
4	Phenytoin Sodium Inj USP250mg /5mL (Phenytoin Sodium Injection USP 50mg/mL - 250mg of bulk drug filled in 5mL Vial and capped with 13mm Rubber Stopper & 13mm	91800 Numbers	4	13FO LQ 3768 GREEN MATTE TOP (13mm Green Color Matte Finish Flip Off Seals)	Relevant as per Packing Policy

	Green colour Matte finish Seals)				
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RA concerned may take further necessary action as per above decision of NC.

Case No.	168 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	VENOR PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000455AM23
RA File Number	05AX04000735 AM22
Licence No and Date	0511012122/27/04/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/8 dated 23.09.2022** against advance authorization No. **0511004978 dated 27.09.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Tablet Morphine Sulphate 10 mg (NR/PR/CR)(Finished formulation of Morphine Sulphate)	1 Number	1	Morphine Sulphate	10.2 mg
2	Tab. Morphine Sulphate 20 mg (NR/PR/CR)(Finished formulation of Morphine Sulphate)	1 Number	2	Morphine Sulphate	20.4 mg
3	Tab. Morphine Sulphate 30 mg (NR/PR/CR)(Finished Formulation of Morphine Sulphate)	1 Number	3	Morphine Sulphate	30.6 mg
4	Tab. Morphine Sulphate 15 mg (NR/CR/PR)(Finished formulation of Morphine Sulphate)	1 Number	4	Morphine Sulphate	15.3 mg
5	Inj. Morphine Sulphate 10 mg/ml, 1ml	1 Number	5	Morphine Sulphate	11.00 mg

	Ampoule(Finished Formulation of Morphine Sulphate)				
6	Inj. Morphine Sulphate 15mg/ml, 1 ml Ampoule(Finished Formulation of Morphine Sulphate)	1 Number	6	Morphine Sulphate	16.5 mg
7	Tab. Morphine Sulphate 60 mg (NR/CR/PR)(Finished Formulation of Morphine Sulphate)	1 Number	7	Morphine Sulphate	61.20 mg

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

Case No.	169 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000445AM23
RA File Number	03AX04000383 AM23
Licence No and Date	0311014211/27/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	170 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000450AM23
RA File Number	05AX04000232 AM23
Licence No and Date	0511012110/27/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	171 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	SENTISS PHARMA PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022

and Date			
HQ File Number	HQRNORM APPLY 00000451AM23		
RA File Number	05AX04000231 AM23		
Licence No and Date	0511012109/27/04/2022		
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. 3/82-ALC4/2015 dated 20.05.2015 against advance authorization No. 0510390257 dated 11.08.2014, 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.	Import items
Xonef Eye Drops / Betaxolol 0.5% Eye Drops 5ml Vials		1 Vial	Betaxolol Hydrochloride 28.52 mg / 5 ml Vial
RA concerned may take further necessary action as per above decision of NC.			

Case No.	172 / NC/3/MEET/Nov/202223/12				
Case Status	Case Approved				
Party Name	VENOR PHARMA LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022				
HQ File Number	HQRNORM APPLY 00000454AM23				
RA File Number	05AX04000738 AM22				
Licence No and Date	0511012121/27/04/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/202223/8 dated 23.09.2022 against advance authorization No. 0511004978 dated 27.09.2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Tablet Morphine Sulphate 10 mg (NR/PR/CR)(Finished formulation of	1 Number	1	Morphine Sulphate	10.2 mg

	Morphine Sulphate)				
2	Tab. Morphine Sulphate 20 mg (NR/PR/CR)(Finished formulation of Morphine Sulphate)	1 Number	1	Morphine Sulphate	20.4 mg
3	Tab. Morphine Sulphate 30 mg (NR/PR/CR)(Finished Formulation of Morphine Sulphate)	1 Number	1	Morphine Sulphate	30.6 mg
4	Tab. Morphine Sulphate 15 mg (NR/CR/PR)(Finished formulation of Morphine Sulphate)	1 Number	1	Morphine Sulphate	15.3 mg
5	Inj. Morphine Sulphate 10 mg/ml, 1ml Ampoule (Finished Formulation of Morphine Sulphate)	1 Number	1	Morphine Sulphate	11.00 mg
6	Inj. Morphine Sulphate 15mg/ml, 1 ml Ampoule (Finished Formulation of Morphine Sulphate)	1 Number	1	Morphine Sulphate	16.5 mg

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

Case No.	173 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	UNITED BIOCEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000479AM23
RA File Number	05AX04000238 AM23
Licence No and Date	0511012150/28/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	174 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000483AM23
RA File Number	03AX04000200 AM23
Licence No and Date	0311014256/28/04/2022
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.	

Case No.	175 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000502AM23
RA File Number	09AX04000389 AM22
Licence No and Date	0911002926/29/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	176 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000506AM23
RA File Number	09AX04000079 AM23
Licence No and Date	0911002928/29/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	177 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000512AM23
RA File Number	08AX04000074 AM23
Licence No and Date	0811004832/29/04/2022

Norms Committee Decision:
Deferred for comments of TE.

Case No.	178 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	HARMAN FINOCHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000485AM23
RA File Number	03AX04000399 AM23
Licence No and Date	0311014263/29/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	179 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000513AM23
RA File Number	08AX04000823 AM22
Licence No and Date	0811004833/29/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	180 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	CHIRO PHARMA
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000495AM23
RA File Number	30AX04000016 AM23
Licence No and Date	3011002069/29/04/2022
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.
Ampicillin Tablets USP 1000 mg((Each film coated tablet contains Ampicillin Trihydrate eq. to ampicillin 1000 mg))	1 Number	1	Ampicillin Trihydrate	1154 mg / 1000 mg Tablet

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

Case No.	181 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MAKCUR LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000499AM23
RA File Number	08AX04000097 AM23
Licence No and Date	0811004820/29/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	182 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000500AM23
RA File Number	09AX04000372 AM22
Licence No and Date	0911002924/29/04/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	183 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SAINOR LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000501AM23
RA File Number	09AX04000388 AM22
Licence No and	0911002925/29/04/2022

Date	
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	184 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000532AM23
RA File Number	09AX04000395 AM22
Licence No and Date	0911002933/02/05/2022

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. **0911001814 dated 03.11.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
(2S,3S,5S)-2-amino-3-hydroxy-5-tert butyl carbonyl amino-1,6-diphenyl-hexane((2S,3S,5S)-2-amino-3-hydroxy-5-tert butyl carbonyl amino-1,6-diphenyl-hexane)	1 kg	1	(S,E)-5-AMINO-2-(DIBENZYLAMINO)-1,6-DIPHENYLHEX-4-EN-3-ONE	1.77 kg
		2	SODIUM BORO HYDRIDE	0.45 kg
		3	TETRA HYDRO FURAN	0.48 kg
		4	2,2,2 TRI FLUORO ACETIC ACID	2.16 kg
		5	DI TERT.BUTYL DI CARBONATE	0.92 kg

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

Case No.	185 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022

and Date	
HQ File Number	HQRNORM APPLY 00000535AM23
RA File Number	31AX04000023 AM23
Licence No and Date	3111001324/02/05/2022
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. Composition given in the Export Product No. 1, 2, 5 and 6 are not matching with the given DML. Please furnish relevant DML for all the export products.	

Case No.	186 / NC/3/MEET/Nov/202223/12													
Case Status	Case Approved													
Party Name	HETERO LABS LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022													
HQ File Number	HQRNORM APPLY 00000537AM23													
RA File Number	09AX04000087 AM23													
Licence No and Date	0911002931/02/05/2022													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td rowspan="2">DOLUTEGRAVIR SODIUM</td><td rowspan="2">1 kg</td><td>1</td><td>(4R,12AS)-7-METHXOY-4-METHYL-6,8-DIOXO-3,4,6,8,12,12A-HEXAHYDRO-2H-PYRIDO 1',2',4,5] YRAZINO [2,1-B][1,3]OXAZINE-9-CARBOXILIC ACID</td><td>0.90 kg</td></tr><tr><td>2</td><td>2,4-DIFLUOROBENZYLAMINE</td><td>0.426 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	DOLUTEGRAVIR SODIUM	1 kg	1	(4R,12AS)-7-METHXOY-4-METHYL-6,8-DIOXO-3,4,6,8,12,12A-HEXAHYDRO-2H-PYRIDO 1',2',4,5] YRAZINO [2,1-B][1,3]OXAZINE-9-CARBOXILIC ACID	0.90 kg	2	2,4-DIFLUOROBENZYLAMINE	0.426 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
DOLUTEGRAVIR SODIUM	1 kg	1	(4R,12AS)-7-METHXOY-4-METHYL-6,8-DIOXO-3,4,6,8,12,12A-HEXAHYDRO-2H-PYRIDO 1',2',4,5] YRAZINO [2,1-B][1,3]OXAZINE-9-CARBOXILIC ACID	0.90 kg										
		2	2,4-DIFLUOROBENZYLAMINE	0.426 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	187 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved

Party Name	AUROBINDO PHARMA LTD										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022										
HQ File Number	HQRNORM APPLY 00000538AM23										
RA File Number	09AX04000065 AM23										
Licence No and Date	0911002947/02/05/2022										
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 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>Cefalexin Tablets 500mg (Cefalexin Tablets 500mg (Each tablet contains Cefalexin Monohydrate equivalent to Cefalexin 500mg)))</td><td>1 Number</td><td>1</td><td>Cefalexin Monohydrate Ph Eur (Powder)</td><td>536.4 mg / 500 mg Tablet</td></tr> </tbody> </table>		Export product	Qty.	Sl. No.	Import items	Qty.	Cefalexin Tablets 500mg (Cefalexin Tablets 500mg (Each tablet contains Cefalexin Monohydrate equivalent to Cefalexin 500mg)))	1 Number	1	Cefalexin Monohydrate Ph Eur (Powder)	536.4 mg / 500 mg Tablet
Export product	Qty.	Sl. No.	Import items	Qty.							
Cefalexin Tablets 500mg (Cefalexin Tablets 500mg (Each tablet contains Cefalexin Monohydrate equivalent to Cefalexin 500mg)))	1 Number	1	Cefalexin Monohydrate Ph Eur (Powder)	536.4 mg / 500 mg Tablet							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	188 / NC/3/MEET/Nov/202223/12										
Case Status	Case Approved										
Party Name	OPTIMUS DRUGS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022										
HQ File Number	HQRNORM APPLY 00000519AM23										
RA File Number	09AX04000060 AM23										
Licence No and Date	0911002929/02/05/2022										
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 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>(1R,2R)-2-Amino-6-(4-</td><td>1 kg</td><td>1</td><td>Di Tert Butyl Dicarbonate</td><td>3.16 kg</td></tr> </tbody> </table>		Export product	Qty.	Sl. No.	Import items	Qty.	(1R,2R)-2-Amino-6-(4-	1 kg	1	Di Tert Butyl Dicarbonate	3.16 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
(1R,2R)-2-Amino-6-(4-	1 kg	1	Di Tert Butyl Dicarbonate	3.16 kg							

Nitrophenyl)-1-Phenylhex-5-yn-1-ol Hydrochloride		2	CDX-034 Lyophilized Enzyme Powder	0.012 kg
		3	Beta Nicotinamide Adenine dinucleotide phosphate Sodium salt (beta-NADP-Na)	0.008 kg
		4	N-Heptane	3.00 kg
		5	Tetra Hydro Furan	5.00 kg
		6	Iso Propyl Alcohol	10.00 kg
		7	Methyl Tertiary-Butyl Ether	3.50 kg

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

Case No.	189 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	MANGALAM ORGANICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00000520AM23			
RA File Number	03AX04000222 AM23			
Licence No and Date	0311014302/02/05/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. 13/82-ALC4/2019 dated 31.01.2020 against advance authorization No. 0310833490 dated 18.12.2019 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

Case No.	190 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000522AM23
RA File Number	09AX04000392 AM22
Licence No and Date	0911002892/02/05/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Aug/202223/6 dated 09.09.2022** against advance authorization No. **0911002160 dt. 31.12.2021**, it was decided to ratify 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.
(2S,3S,5S)-2-amino-3-hydroxy-5-tert butyl carbonyl amino-1,6-diphenyl-hexane((2S,3S,5S)-2-amino-3-hydroxy-5-tert butyl carbonyl amino-1,6-diphenyl-hexane)	1 kg	1	(S,E)-5-AMINO-2-(DIBENZYLAMINO)-1,6-DIPHENYLHEX-4-EN-3-ONE	1.77 kg
		2	SODIUM BORO HYDRIDE	0.45 kg
		3	TETRA HYDRO FURAN	0.48 kg
		4	2,2,2 TRI FLUORO ACETIC ACID	2.16 kg
		5	DI TERT.BUTYL DI CARBONATE	0.92 kg

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

Case No.	191 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000531AM23
RA File Number	26AX04000006 AM23
Licence No and	2611000569/02/05/2022

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: Master Batch Formula duly certified by Quality Control in Charge.	

Case No.	192 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000548AM23
RA File Number	03AX04000420 AM23
Licence No and Date	0311014381/04/05/2022
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.	

Case No.	193 / NC/3/MEET/Nov/202223/12				
Case Status	Case Approved				
Party Name	GLOBAL CALCIUM PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022				
HQ File Number	HQRNORM APPLY 00000552AM23				
RA File Number	07AX04000126 AM23				
Licence No and Date	0711003904/04/05/2022				
Norms Committee Decision:					
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. 6/82-ALC4/2019 dated 16.08.2019 against advance authorization No. 0710115110 dated 27.06.2019 , 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:					
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	MAGNESIUM PIDOLATE (Eur.Ph) (MAGNESIUM PIDOLATE (Eur.Ph))	1 MT	1	L-PYROGLUTAMIC ACID	0.90 MT

2	CALCIUM PIDOLATE (CALCIUM PIDOLATE)	1 MT	2	L-PYROGLUTAMIC ACID	0.82 MT
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RA concerned may take further necessary action as per above decision of NC.

Case No.	194 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000559AM23
RA File Number	09AX04000086 AM23
Licence No and Date	0911002930/04/05/2022

Norms Committee Decision:

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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.
DOLUTEGRAVIR SODIUM	1 kg	1	(4R,12AS)-7-METHXOY-4-METHYL-6,8-DIOXO-3,4,6,8,12,12A-HEXAHYDRO-2H-PYRIDO [1',2',4,5]PYRAZINO [2,1-B][1,3] OXAZINE-9-CARBOXILIC ACID	0.90 kg
		2	2,4-DIFLUOROBENZYLAMINE	0.426 kg

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

Case No.	195 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	DR.REDDY'S LABORATORIES LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000575AM23
RA File Number	09AX04000107 AM23
Licence No and	0911002951/04/05/2022

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Daptomycin for Injection 500mg/vial	1 Number	1	Daptomycin	550 mg / Vial
RA concerned may take further necessary action as per above decision of NC.				

Case No.	196 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	AUROBINDO PHARMA LTD			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00000579AM23			
RA File Number	09AX04000072 AM23			
Licence No and Date	0911002953/05/05/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jul/202122/4 dated 15/07/2021 against advance authorization No. 0911000214 dated 20/01/2021 , it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Clavamox Drops 62.50 mg/mL - 15mL((Each mL contains Amoxicillin Trihydrate equivalent to Amoxicillin 50 mg and Clavulanate potassium syloid 1:1 equivalent to Clavulanic acid 12.5mg))	3276000 Numbers	1	Amoxicillin Trihydrate	2876.055 kg
		2	Potassium Clavulanate diluted with Silicon Dioxide (Syloid)(1:1)	1492.739 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	197 / NC/3/MEET/Nov/202223/12													
Case Status	Case Approved													
Party Name	WANKSONS CHEMICALS INDUSTRIES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022													
HQ File Number	HQRNORM APPLY 00000590AM23													
RA File Number	03AX04000353 AM23													
Licence No and Date	0311014492/05/05/2022													
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Dec/202122/12 dated 17/12/2021 against advance authorization No. 0311005179 dated 07/07/2021, 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: <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>CHLORAL</td> <td>1 kg</td> <td>1</td> <td>ETHYL ALCOHOL</td> <td>0.878 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.	CHLORAL	1 kg	1	ETHYL ALCOHOL	0.878 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
CHLORAL	1 kg	1	ETHYL ALCOHOL	0.878 kg										

Case No.	198 / NC/3/MEET/Nov/202223/12			
Case Status	Case Deferred			
Party Name	SHREYANS CHEMICALS			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00000593AM23			
RA File Number	03AX04000546 AM23			
Licence No and Date	0311014500/05/05/2022			
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. Justification for low yield of 61.6%. iii. Production / Consumption data for last two years duly certified by GST.				

Case No.	199 / NC/3/MEET/Nov/202223/12										
Case Status	Case Approved										
Party Name	DR.REDDY'S LABORATORIES LTD										
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022										
HQ File Number	HQRNORM APPLY 00000599AM23										
RA File Number	09AX04000351 AM22										
Licence No and Date	0911002964/05/05/2022										
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jul/202122/4 dated 15/07/2021 against advance authorization No. 0911000447 dated 26/02/2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: <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>Daptomycin for Injection 500mg/vial</td> <td>1 Number</td> <td>1</td> <td>Daptomycin</td> <td>550 mg / Vial</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.	Daptomycin for Injection 500mg/vial	1 Number	1	Daptomycin	550 mg / Vial
Export product	Qty.	Sl. No.	Import items	Qty.							
Daptomycin for Injection 500mg/vial	1 Number	1	Daptomycin	550 mg / Vial							

Case No.	200 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000601AM23
RA File Number	07AX04000602 AM22
Licence No and Date	0711003913/05/05/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis.	

v. Details of indigenous input with quantity.

Case No.	201 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000633AM23
RA File Number	07AX04000046 AM23
Licence No and Date	0711003906/06/05/2022
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. COA report of both import and export item, clearly indicating purity and moisture content. ii. Manufacturing process indicating stage wise wastage of raw materials. iii Production / Consumption data duly certified by CA.	

Case No.	202 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000634AM23
RA File Number	07AX04000114 AM23
Licence No and Date	0711003926/06/05/2022
Norms Committee Decision: Deferred for comments of TE.	

Case No.	203 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000635AM23
RA File Number	07AX04000115 AM23
Licence No and Date	0711003928/06/05/2022
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	204 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	RUBICON RESEARCH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000612AM23
RA File Number	03AX04000440 AM23
Licence No and Date	0311014526/06/05/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Oct/202223/11 dated 31/10/2022** against advance authorization No. **0311009414 dated 13/12/2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Maxigesic cold & flu Hot Drink 500mg/150mg Sachets (Paracetamol & Ibuprofen Sachets 500 mg & 150 mg)(Maxigesic cold & flu Hot Drink 500mg/150mg Sachets (Paracetamol & Ibuprofen Sachets 500 mg & 150 mg) No. of Sachets 170,000 (Net content of Ibuprofen Lysine Salt IH API 43.61 kg))	1 Number	1	Ibuprofen Lysine Salt IH	258.88 mg / Sachet
2	Maxigesic cold & flu Hot Drink 1000mg/300mg Sachets (Paracetamol & Ibuprofen Sachets 1000 mg & 300 mg)(Maxigesic cold & flu Hot Drink 1000mg/300mg Sachets (Paracetamol & Ibuprofen Sachets 1000 mg & 300 mg) No. of Sachets 280,000 (Net content of Ibuprofen Lysine Salt IH API 143.64 kg))	1 Number	2	Ibuprofen Lysine Salt IH	517.77 mg / Sachet

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

Case No.	205 / NC/3/MEET/Nov/202223/12
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Case Status	Case Deferred
Party Name	APTRA SYNTHESIS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000622AM23
RA File Number	26AX04000005 AM23
Licence No and Date	2611000572/06/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	206 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000628AM23
RA File Number	09AX04000048 AM23
Licence No and Date	0911002943/06/05/2022
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:	

Case No.	207 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	JUBILANT INGREVIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000676AM23

RA File Number	05AA04033196 AM21			
Licence No and Date	0511012352/09/05/2022			
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-ALC4/2018 dated 16.05.2018 against advance authorization No. 0510398839 dated 17.06.2016, 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 Picoline	1 kg	1	Denatured Ethyl Alcohol	3.90 kg
		2	Ammonia	0.90 kg
		3	Catalyst (CP7191)	0.0025 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	208 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000716AM23
RA File Number	52AX04000029 AM23
Licence No and Date	5211002458/11/05/2022
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. Reason for indicating Ethyl-3-oxobutanoate in place of Ethyl Aceto Acetate in chemical reaction and also difference in two chemicals. ii. Reason with justification for low yield of export item. iii. Commercial value of By-Product obtained during the process and its enclosed invoice.	

Case No.	209 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved

Party Name	STERILE INDIA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00000717AM23			
RA File Number	05AX04000343 AM23			
Licence No and Date	0511012466/11/05/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Dec/202122/12 dated 17/12/2021 against advance authorization No. 0511003790 dated 23/07/2021, 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.
Ceftriaxone Sodium Sterile	1 kg	1	Ceftriaxone Sodium Non Sterile	1.04 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	210 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000720AM23
RA File Number	08AX04000212 AM23
Licence No and Date	0811004914/11/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	211 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000703AM23
RA File Number	09AX04000059 AM23
Licence No and Date	0911002979/11/05/2022

Norms Committee Decision:

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

i. **DML.**

ii **Potency of import item supported by COA from foreign supplier.**

Case No.	212 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000708AM23
RA File Number	26AX04000007 AM23
Licence No and Date	2611000574/11/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	213 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	CLEAN SCIENCE AND TECHNOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000711AM23
RA File Number	31AX04000042 AM23
Licence No and Date	3111001345/11/05/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information /documents from the firm:	
i. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.	

Case No.	214 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022

HQ File Number	HQRNORM APPLY 00000715AM23
RA File Number	03AX04000356 AM23
Licence No and Date	0311014646/11/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	215 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000727AM23
RA File Number	03AX04000667 AM23
Licence No and Date	0311014663/12/05/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis. Details of indigenous input with quantity.	

Case No.	216 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	BIOXERA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000729AM23
RA File Number	03AX04000618 AM23
Licence No and Date	0311014664/12/05/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Apr/202223/1 dated 29.04.2022 against advance authorization No. 0311009297 dated 08.12.2021, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Export product	Qty.	Sl. No.	Import items	Qty.
BENFOTIAMINE	1 kg	1	VITAMIN B1	0.922 kg

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

Case No.	217 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000730AM23
RA File Number	03AX04000676 AM23
Licence No and Date	0311014666/12/05/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: End use of Export Product. Whether DMSO is used as a solvent or reactant. If DMSO used as a reactant, then please furnish the details of its molecular weight. If DMSO is used as a solvent, then furnish the details of its recovery. Quantity and value of Methanol as a By-Product. Stoichiometric balance on molar basis. Yield at every stage of reaction.	

Case No.	218 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000732AM23
RA File Number	05AX04000321 AM23
Licence No and Date	0511012512/12/05/2022
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Aug/202223/6 dated 09.09.2022 against advance authorization No. 0510413419 dated 22.01.2020, 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.
Easy Five TT Vaccine DTwP-Hep B-Hib-Pentavalent Vaccine (Each vial of 0.5 ml contains 1 dose)	1 Million Vials	1	Purified Diptheria Toxoid Concentrate Antigen Bulk @2050 Lf/ml	13.33 Litre
		2	Purified Tetanus Toxoid Concentrate Antigen @1900 Lf/ml	5.23 Litre
		3	Inactivated Whole Cell Pertussis Bulk @192 OU/ml	86.46 Litre
		4	Rubber Stopper	1010000 Numbers
		5	AGS HB Purification MABS Column	5.4 Litre
		6	Tetanus Toxoid for conjugation	6.15 Litre

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

Case No.	219 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000750AM23
RA File Number	34AX04000127 AM23
Licence No and Date	3411002246/13/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	220 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022

HQ File Number	HQRNORM APPLY 00000753AM23
RA File Number	52AX04000039 AM23
Licence No and Date	5211002485/13/05/2022
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. Function / Application of Dimethyl Formamide and to give complete process of using the solvent. ii. Reason with justification for applying very high quantity of Dimethyl Formamid iii. Recovery process of Dimethyl Formamide.	

Case No.	221 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000756AM23
RA File Number	09AX04000102 AM23
Licence No and Date	0911002994/13/05/2022
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:	

		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.	222 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	UNITED BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000757AM23
RA File Number	05AX04000267 AM23
Licence No and Date	0511012548/13/05/2022
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 its comments.	

Case No.	223 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000741AM23
RA File Number	07AX04000110 AM23
Licence No and Date	0711003978/13/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	224 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	NAVIN FLUORINE INTERNATIONAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000801AM23
RA File Number	03AX04000672 AM23
Licence No and Date	0311014751/17/05/2022

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. Justification for low yield in Hydrogenation reaction.**
- iii. Quantity and Commercial Value of Isometric impurities (As By-Product).**

iv Stoichiometric balance on molar basis and percentage yield to arrive at the quantity of raw material asked for.

Case No.	225 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	KOSHA CHEMTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000806AM23
RA File Number	03AX04000276 AM23
Licence No and Date	0311014758/17/05/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was 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.	226 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000807AM23
RA File Number	31AX04000028 AM23
Licence No and Date	3111001358/17/05/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product /

import item in Meeting No. **NC/3/MEET/Sep/202223/8 dated 23.09.2022** against advance authorization No. **3110067490 dated 02.08.2019**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

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

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

Case No.	227 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000815AM23
RA File Number	31AX04000039 AM23
Licence No and Date	3111001366/17/05/2022

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:

- i. **Give separate quantity of Phenol and O-Cresol in OCP-50 and then drive the quantity of 2, 6 Xylenol from both.**
- ii. **Complete calculation of formulation of 2, 6 Xylenol from both with yield.**

Case No.	228 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	FINE ORGANIC INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022

HQ File Number	HQRNORM APPLY 00000792AM23			
RA File Number	03AX04000631 AM23			
Licence No and Date	0311014729/17/05/2022			
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. 1/82-ALC4/2018 dated 01.05.2018 against advance authorization No. 0310812799 dated 26.04.2017, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Neutralized Amide Ester	1 kg	1	STEARIC ACID	1.06 kg
		2	Mono Ethanol Amine	0.114 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	229 / NC/3/MEET/Nov/202223/12			
Case Status	Case Approved			
Party Name	AARTI DRUGS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022			
HQ File Number	HQRNORM APPLY 00000794AM23			
RA File Number	03AX04000640 AM23			
Licence No and Date	0311014736/17/05/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Sep/202223/8 dated 23.09.2022 against advance authorization No. 0311004037 dated 25.05.2021, 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.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg

		2	Piperazine Anhydrous	0.390 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	230 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ANUH PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000796AM23
RA File Number	03AX04000377 AM23
Licence No and Date	0311014743/17/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	231 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000797AM23
RA File Number	03AX04000463 AM23
Licence No and Date	0311014744/17/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	232 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SHIVA BIO CHEM INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000856AM23
RA File Number	50AX04000018 AM23
Licence No and Date	5011000486/18/05/2022
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. COA of import and export item indicating percentage purity.
 ii. If any, By-Product obtained, please furnish details of quantity and value of such Product.

By-

End use of Export Product.

Case No.	233 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000874AM23
RA File Number	03AX04000715 AM23
Licence No and Date	0311014851/19/05/2022

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/May/202223/3 dated 27/05/2022** against advance authorization No. **0310814635 dated 14.07.2017**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No	Import items	Qty.
1	Benzylamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and(all other flavours. Each lozenge contains (i) Benzylamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride-1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 33.333 Kgs (ii) 14.778 Kgs (iii) 28733.356 Kgs.)	1000 Number	1.	Benzylamine Hydrochloride	3.06 gram
			2	Cetylpyridinium Chloride	1.356 gram
			3	Isomalt ST-M	2586 gram
2	Benzylamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzylamine	1000 Number	4	Benzylamine Hydrochloride	3.06 gram
			5	Isomalt ST-M	2586 gram

	Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg. Net content (i) 21.333 Kgs. (ii) 18389.439 Kgs.)				
3	Benzylamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free. Each lozenge contains (i) Benzylamine Hydrochloride-(3mg (ii) Isomalt ST-M - 2586mg. Net content (i) 12 Kgs. (ii) 10344 Kgs.)	1000 Number	6	Benzylamine Hydrochloride	3.06 gram
			7	Isomalt ST-M	2586 gram
4	Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 13.333 Kg (ii) 25924.878 Kg)	1000 Number	8	Cetylpyridinium Chloride	1.356 gram
			9	Isomalt ST-M	2586 gram
5	Cetylpyridinium Chloride And Benzylamine Hydrochloride Antiseptic Lozenges Sugar Free. Each lozenge contains((i) Cetylpyridinium Chloride- 1mg (ii) Isomalt ST-M - 2586mg. Net content (i) 5.22 Kg (ii) 13498.92 Kg)	1000 Number	10	Cetylpyridinium Chloride	1.02 gram
			11	Isomalt ST-M	2586 gram

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

Case No.	234 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000875AM23
RA File Number	03AX04000406 AM23
Licence No and Date	0311014852/19/05/2022

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/May/202223/3 dated 27/05/2022** against advance authorization No. **0310814635 dated 14.07.2017**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No	Import items	Qty.
1	Benzylamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and(all other flavours. Each lozenge contains (i) Benzylamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride-1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 33.333 Kgs (ii) 14.778 Kgs (iii) 28733.356 Kgs.)	1000 Number	1.	Benzylamine Hydrochloride	3.06 gram
			2	Cetylpyridinium Chloride	1.356 gram
			3	Isomalt ST-M	2586 gram
2	Benzylamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzylamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg. Net content (i) 21.333 Kgs. (ii) 18389.439 Kgs.)	1000 Number	4	Benzylamine Hydrochloride	3.06 gram
			5	Isomalt ST-M	2586 gram
3	Benzylamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free. Each lozenge contains (i) Benzylamine Hydrochloride-(3mg (ii) Isomalt ST-M - 2586mg. Net content (i) 12 Kgs. (ii) 10344 Kgs.)	1000 Number	6	Benzylamine Hydrochloride	3.06 gram
			7	Isomalt ST-M	2586 gram
4	Cetylpyridinium Chloride And Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium	1000 Number	8	Cetylpyridinium Chloride	1.356 gram
			9	Isomalt ST-M	2586 gram

	Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 13.333 Kg (ii) 25924.878 Kg)				
5	Cetylpyridinium Chloride And Benzydamine Hydrochloride Antiseptic Lozenges Sugar Free. Each lozenge contains((i) Cetylpyridinium Chloride- 1mg (ii) Isomalt ST-M - 2586mg. Net content (i) 5.22 Kg (ii) 13498.92 Kg)	1000 Number	10	Cetylpyridinium Chloride	1.02 gram
			11	Isomalt ST-M	2586 gram

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

Case No.	235 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ALG CHEMICALS.
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000883AM23
RA File Number	03AX04000006 AM23
Licence No and Date	0311014857/19/05/2022

Norms Committee Decision:

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

- i. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.**
- ii. Justification for wastage.**
- iii. Production / Consumption data duly certified by CA.**
- iv. Indicate the By-Product with their Commercial Value.**

Case No.	236 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000884AM23

RA File Number	03AX04000407 AM23
Licence No and Date	0311014858/19/05/2022

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/May/202223/3 dated 27/05/2022** against advance authorization No. **0310814635 dated 14.07.2017**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No	Import items	Qty.
1	Benzylamine Hydrochloride And Cetylpyridinium Chloride Anti-Inflammatory And Antiseptic Lozenges Sugar Free and(all other flavours. Each lozenge contains (i) Benzylamine Hydrochloride-3mg (ii) Cetylpyridinium Chloride-1.33mg (iii) Isomalt ST-M - 2586mg. Net content (i) 33.333 Kgs (ii) 14.778 Kgs (iii) 28733.356 Kgs.)	1000 Number	1.	Benzylamine Hydrochloride	3.06 gram
			2	Cetylpyridinium Chloride	1.356 gram
			3	Isomalt ST-M	2586 gram
2	Benzylamine Hydrochloride, 2,4-Dichlorobenzyl Alcohol And Lidocaine Hydrochloride Anaesthetic, Anti-Inflammatory,(Anti-Bacterial Lozenges Sugar Free. Each lozenge contains (i) Benzylamine Hydrochloride - 3mg (ii) Isomalt ST-M- 2586mg. Net content (i) 21.333 Kgs. (ii) 18389.439 Kgs.)	1000 Number	4	Benzylamine Hydrochloride	3.06 gram
			5	Isomalt ST-M	2586 gram
3	Benzylamine Hydrochloride Anti-Inflammatory Lozenges Sugar Free. Each lozenge contains (i) Benzylamine Hydrochloride-(3mg (ii) Isomalt ST-M - 2586mg. Net content (i) 12 Kgs. (ii) 10344 Kgs.)	1000 Number	6	Benzylamine Hydrochloride	3.06 gram
			7	Isomalt ST-M	2586 gram
4	Cetylpyridinium Chloride And	1000	8	Cetylpyridinium	1.356 gram

	Bromhexine Hydrochloride Antiseptic Lozenges Sugar Free and all other flavours.(Each lozenge contains (i) Cetylpyridinium Chloride - 1.33mg (ii) Isomalt ST-M - 2586 mg. Net content (i) 13.333 Kg (ii) 25924.878 Kg)	Number		Chloride	
			9	Isomalt ST-M	2586 gram
5	Cetylpyridinium Chloride And Benzylamine Hydrochloride Antiseptic Lozenges Sugar Free. Each lozenge contains ((i) Cetylpyridinium Chloride- 1mg (ii) Isomalt ST-M - 2586mg. Net content (i) 5.22 Kg (ii) 13498.92 Kg)	1000 Number	10	Cetylpyridinium Chloride	1.02 gram
			11	Isomalt ST-M	2586 gram

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

Case No.	237 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000885AM23
RA File Number	52AX04000042 AM23
Licence No and Date	5211002509/19/05/2022

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/May/202223/4 dated 17/06/2022** against advance authorization No. **0311003601 dated 06.05.2021**, 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.
Methyl Paraben	1 kg	1	ParaHydroxy Benzoic Acid	0.97 kg

		2	Methanol	0.50 kg
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RA concerned may take further necessary action as per above decision of NC.

Case No.	238 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000864AM23
RA File Number	07AX04000096 AM23
Licence No and Date	0711003985/19/05/2022

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.
Prochlorperazine Edisylate Injection 10mg/2mL(Prochlorperazine Edisylate Injection 10mg, 2mL vial - 10 mg of bulk drug filled in 2 mL vial and capped with 13mm Rubber Stopper & 13mm Omniflexplus Coated(Dark Grey) Seals)	307800 Numbers	1	110010718 V9239 FM259/0 FLCO 015 (13mm Omniflexplus Coated BB R/S-RFS V9239 FM259/0)	Relevant as per Packing Policy

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

Case No.	239 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000886AM23
RA File Number	07AX04000116 AM23
Licence No and Date	0711003901/19/05/2022

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	Ephedrine Sulfate Injection USP 50mg/mL - 2mL Vial(2mL Vial - filled with 50 mg of Ephedrine Sulfate as bulk drug mixed in water for injection and filled in 2mL Vial and capped with 13mm chlorobutyl Rubber Stopper)	513000 Numbers	1	Grey Westar RS SIL 1 (13mm Chlorobutyle Rubber Stopper Grey RFS)	Relevant as per Packing Policy
2	Cyanocobalamin Injection USP 1000mcg/mL - 2mL Vial(2mL Vial - filled with 1mg of Cyanocobalamin as bulk drug mixed in water for injection and filled in 2mL Vial and capped with 13mm chlorobutyl Rubber Stopper)	360000 Numbers	2	Grey Westar RS SIL 1 (13mm Chlorobutyle Rubber Stopper Grey RFS)	Relevant as per Packing Policy
3	Furosemide Injection 10mg/mL - 2mL Vial(2mL Vial - filled with 20mg of furosemide as bulk drug mixed in water for injection and filled in 2mL Vial and capped with 13mm chlorobutyle Rubber Stopper)	414000 Numbers	3	Grey Westar RS SIL 1 (13mm Chlorobutyle Rubber Stopper Grey RFS)	Relevant as per Packing Policy
4	Furosemide Injection 10mg/mL - 4mL Vial(4mL Vial - filled with 40mg of furosemide as bulk drug mixed in water for injection and filled in 4mL Vial and capped with 13mm chlorobutyle Rubber Stopper)	225000 Numbers	4	Grey Westar RS SIL 1 (13mm Chlorobutyle Rubber Stopper Grey RFS)	Relevant as per Packing Policy

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

Case No.	240 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	KUMAR ORGANIC PRODUCTS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000865AM23
RA File Number	07AX04000056 AM23
Licence No and Date	0711004017/19/05/2022
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.	241 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	MAIVA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000867AM23
RA File Number	07AX04000185 AM23
Licence No and Date	0711004021/19/05/2022

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.
Sterile Water for Injection 10mL Vial	470095 Numbers	1	10ML,23.0X55.5MM,13 A/S 3X (EMPTY VIALS) T2710W02BP	Relevant as per Packing Policy with Accountability Clause

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

Case No.	242 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000906AM23
RA File Number	05AX04000406 AM23
Licence No and Date	0511012696/20/05/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **4/82-ALC4/2018 dated 19.06.2018** against advance authorization No. **0510405547 dated 06.02.2018**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
Tan Endo/ Powder(4-Nitrobenzyl -2- ((1R,5R)-3-benzyl-7-oxo-4-thia-2,6-diazabicyclo[3.2.0]hept-2-en-6-yl)-3-methylbut-2-enoate)	1 kg	1	POTASSIUM PEN G (FIRST CRYSTAL)	1.089 kg
		2	DIMETHYLFORMAMIDE	4.685 kg
		3	TRIETHYLAMINE	0.279 kg
		4	METHYLENE CHLORIDE	2.783 kg
		5	ACETONE	2.525 kg
		6	Toluene	0.852 kg

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

Case No.	243 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	BRAWN LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000909AM23
RA File Number	05AX04000521 AM23
Licence No and Date	0511012700/20/05/2022

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	CIPROFLOXACIN TABLET 250MG((LIGHT YELLOW COLORED, ROUND, BICONVEX, FILM COATED TABLETS))	1 Number	1	CIPROFLOXACIN HYDROCHLORIDE USP	277.50 mg / 250 mg Tablet
2	CIPROFLOXACIN TABLET 500MG((WHITE, ELONGATED, BICONVEX, FLIM COATED TABLETS WITH BREAKLINE ON ONE SIDE))	1 Number	1	CIPROFLOXACIN HYDROCHLORIDE USP	555 mg /500 mg Tablet

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

Case No.	244 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	JODAS EXPOIM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000912AM23
RA File Number	09AX04000058 AM23
Licence No and Date	0911003033/20/05/2022

Norms Committee Decision:

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

- i. **DML.**
- ii. **COA of import item from foreign supplier.**

Wastage applied with calculation.

Case No.	245 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	VISION DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000893AM23
RA File Number	09AX04000124 AM23

Licence No and Date	0911003032/20/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	246 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000901AM23
RA File Number	30AX04000049 AM23
Licence No and Date	3011002146/20/05/2022
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 its comments.	

Case No.	247 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000918AM23
RA File Number	07AX04000117 AM23
Licence No and Date	0711004046/21/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	248 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	METROPOLITAN EXIMCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000920AM23
RA File Number	03AX04000550 AM23
Licence No and Date	0311014915/22/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	249 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000939AM23
RA File Number	07AX04000122 AM23
Licence No and Date	0711004059/23/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	250 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	RECKITT BENCKISER (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000941AM23
RA File Number	05AX04000520 AM23
Licence No and Date	0511012742/23/05/2022

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/202233/8 dated 23.09.2022** against advance authorization No. **0511005203 dated 05.10.2021**, 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.
1	DISPRIN REGULAR (ASPIRIN) PH.EUR 300MG)(ACETYLSALICYLIC ACID 300 mg Tablet (ASPIRIN))	1 Number Tablet	1	CITIRIC ACID ANHYDROUS F4020	30.00 mg
			2	SACCHARIN BASE 55Ox	4.50 mg
			3	CALCIUM CARBONATE EP	90.00 mg
2	DISPRIN,ZA,EXTRA (ASPIRIN) PH.EUR 500MG)(ACETYLSALICYLIC ACID 500 mg Tablet (ASPIRIN))	1 Number Tablet	4	CITIRIC ACID ANHYDROUS F4020	50.00 mg
			5	SACCHARIN BASE 55Ox	7.50 mg
			6	CALCIUM CARBONATE EP	150.00 mg

3	DSPRN,ZA,MELTS,(ASPIRIN PH.EUR 300MG)(ACETYLSALICYLIC ACID 300 mg Tablet (ASPIRIN))	1 Number Tablet	7	SACCHARIN BASE 55Ox	1.00 mg
			8	GLYCINE EP	133.30 mg
4	DSPRN,ZA,DIRECTS,(ASPIRIN PH.EUR 300MG)(ACETYLSALICYLIC ACID 300 mg Tablet (ASPIRIN))	1 Number Tablet	9	SACCHARIN BASE 55Ox	1.00 mg
			10	GLYCINE EP	133.30 mg
5	DISPRIN CARDIOCARE (ASPIRIN BP 100MG)(ACETYLSALICYLIC ACID 100 mg Tablet (ASPIRIN))	1 Number Tablet	11	SACCHARIN BASE 55Ox	0.334 mg
			12	GLYCINE EP	44.40 mg

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

Case No.	251 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000944AM23
RA File Number	09AX04000145 AM23
Licence No and Date	0911003039/23/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	252 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000922AM23
RA File Number	07AX04000113 AM23
Licence No and Date	0711004050/23/05/2022
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. 1/82-ALC4/2018 dated 01/05/2018 against advance authorization No. 0510401908 dt. 09.03.2017, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty.
1	CAFFEINE CITRATE INJECTION 60MG / 3ML(CAFFEINE CITRATE INJECTION 60 MG/3 ML (EQUIVALENT TO 30 MG OF CAFFEINE BASE) EP/BP/USP/IP 24.375 KG)	1 Number	1	CAFFEINE ANHYDROUS	33 mg/3 ml vial
2	CAFFEINE CITRATE ORAL SOLUTION 60 MG / 3 ML (CAFFEINE CITRATE ORAL SOLUTION 60 MG / 3 ML (EQUIVALENT TO 30 MG OF CAFFEINE BASE) BP/EP/USP/IP 15.000 KG)	1 Number	1	CAFFEINE ANHYDROUS	33 mg/3 ml vial

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

Case No.	253 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	UNIMAX CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000924AM23
RA File Number	03AX04000850 AM23
Licence No and Date	0311014924/23/05/2022

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to ratify adhoc norms as per **SION A-2244**.

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

Case No.	254 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000937AM23

RA File Number	30AX04000065 AM23
Licence No and Date	3011002150/23/05/2022
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 its comments.	

Case No.	255 / NC/3/MEET/Nov/202223/12													
Case Status	Case Approved													
Party Name	ENVEE DRUGS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022													
HQ File Number	HQRNORM APPLY 00000950AM23													
RA File Number	34AX04000170 AM23													
Licence No and Date	3411002299/24/05/2022													
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. 0311000563 , 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>BETAMETHASONE SODIUM PHOSPHATE BP/USP/EP(BP/UPS/EP)</td><td>1 kg</td><td>1</td><td>BETAMETHASONE IP BP EP USP</td><td>0.78 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	BETAMETHASONE SODIUM PHOSPHATE BP/USP/EP(BP/UPS/EP)	1 kg	1	BETAMETHASONE IP BP EP USP	0.78 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
BETAMETHASONE SODIUM PHOSPHATE BP/USP/EP(BP/UPS/EP)	1 kg	1	BETAMETHASONE IP BP EP USP	0.78 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	256 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000981AM23
RA File Number	03AX04000820 AM23
Licence No and Date	0311014993/25/05/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in M	

Meeting No. **NC/3/MEET/Jan/202021/4 dated 12/02/2021** against advance authorization No. **0310836157 dated 11.05.2020**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export Product	Qty	Sl. No.	Import Items	Qty
1	Cetylpyridinium Chloride, Benzydamine Hydrochloride and Pholcodine Lozenges Sugar Free Blackcurrant/ Pineapple & Lime/(Honey, Lemon & Ginger/Other Flavours. Each Lozenge contains (i) Pholcodine 5.50mg (ii) Benzydamine Hydrochloride 1.50 mg (iii) Cetylpyridinium Chloride 1.33 mg (iv) Isomalt ST-M 2583 mg. Net Content (i) 43.80 kg (ii) 11.94 kg (iii) 10.59 kg (iv) 20568 Kg)	1 Number	1	Pholcodine	5.61 mg
			2	Benzydamine Hydrochloride	1.53mg
			3	Cetylpyridinium Chloride	1.357 mg
			4	Isomalt ST-M	2583.0 mg
2	Pholcodine and Cetylpyridinium Chloride Lozenges Sugar Free Orange / Lemon and Other Flavours. Each Lozenge contains (i) Pholcodine 5.50 mg (ii) Cetylpyridinium Chloride 1.33 mg (iii) Isomalt ST-M 2579 mg. Net Content (i) Pholcodine-30.77 kg (ii) Cetylpyridinium Chloride-7.44 kg (iii) Isomalt ST-M-14427.96 kg.)	1 Number	5	Pholcodine	5.61 mg
			6	Cetylpyridinium Chloride	1.357 mg
			7	Isomalt ST-M	2579.0 mg

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

Case No.	257 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000982AM23
RA File Number	03AX04000697 AM23
Licence No and Date	0311014994/25/05/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/8 dated 23.09.2022** against advance authorization No. **0311004037 dated 25.05.2021**, 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.
Ciprofloxacin Hydrochloride BP/EP/USP (Ciprofloxacin)	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-5Fluorobenzoyl) Acrylate	1.240 kg
		2	Piperazine Anhydrous	0.390 kg

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

Case No.	258 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	DHANUKA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000987AM23
RA File Number	05AX04000414 AM23
Licence No and Date	0511012794/25/05/2022
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. Percentage purity of export item. COA of export item.	

Case No.	259 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ASSOCIATED DYESTUFF PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000991AM23
RA File Number	08AX04000268 AM23
Licence No and Date	0811005014/25/05/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information/documents from the	

firm:

- i. **Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis.**
- ii. **By-Product and its value.**

Justification for wastage.

Case No.	260 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	HETERO DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000975AM23
RA File Number	09AX04000080 AM23
Licence No and Date	0911003042/25/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	261 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000976AM23
RA File Number	09AX04000136 AM23
Licence No and Date	0911003043/25/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	262 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SRINI PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000978AM23
RA File Number	09AX04000133 AM23
Licence No and Date	0911003044/25/05/2022
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	263 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000980AM23
RA File Number	03AX04000822 AM23
Licence No and Date	0311014992/25/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	264 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001004AM23
RA File Number	05AX04000553 AM23
Licence No and Date	0511012820/26/05/2022
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information/documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. Complete technical details as per Annexure to Appendix 4E for chemical products. Stoichiometric balance between import and export on molar basis. Details of indigenous input with quantity.	

Case No.	265 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	SOLARA ACTIVE PHARMA SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001010AM23
RA File Number	04AX04000178 AM23
Licence No and	0411003383/26/05/2022

Date	
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	266 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000992AM23
RA File Number	09AX04000139 AM23
Licence No and Date	0911003051/26/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	267 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00000995AM23
RA File Number	09AX04000148 AM23
Licence No and Date	0911003052/26/05/2022

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.
(1R,2R)-2-Amino-6-(4-Nitrophenyl)-1-Phenylhex-5-yn-1-ol Hydrochloride	1 kg	1	Di Tert Butyl Dicarboxate	3.16 kg
		2	CDX-034 Lyophilized Enzyme Powder	0.012 kg
		3	Beta Nicotinamide Adenine dinucleotide phosphate Sodium salt (beta-NADP-Na)	0.008 kg
		4	N-Heptane	3.00 kg

		5	Tetra Hydro Furan	5.00 kg
		6	Iso Propyl Alcohol	10.00 kg
		7	Methyl Tertiary-Butyl Ether	3.50 kg

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

Case No.	268 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001000AM23
RA File Number	07AX04000159 AM23
Licence No and Date	0711004100/26/05/2022

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. **0711000830 dated 05.04.2021**, 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.
DICLOXACILLIN CAPSULES DICLOXACILLIN CAPSULES 500 MG BP/EP/IP/USP 1999.99 KG)	3999990 Numbers	1	DICLOXACILLIN SODIUM	2140 kg

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

Case No.	269 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022

HQ File Number	HQRNORM APPLY 00001002AM23
RA File Number	07AX04000209 AM23
Licence No and Date	0711004103/26/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	270 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001012AM23
RA File Number	03AX04000926 AM23
Licence No and Date	0311015038/27/05/2022
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:	

Case No.	271 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	NEOGEN CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001015AM23
RA File Number	03AX04000924 AM23
Licence No and Date	0311015041/27/05/2022
Norms Committee Decision:	

Deferred for comments of TE.

Case No.	272 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001016AM23
RA File Number	03AX04000627 AM23
Licence No and Date	0311015042/27/05/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/202122/13 dated 21.01.2022** against advance authorization No. **0311006599 dated 01.09.2021**, it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Alverine Citrate 120mg Hard Capsules	1 Number	1	Alverine Citrate	122.40 mg / Capsule
2	Alverine Citrate 60mg Hard Capsules	1 Number	2	Alverine Citrate	61.20 mg / Capsule

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

Case No.	273 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	AUROBINDO PHARMA LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001038AM23
RA File Number	09AX04000156 AM23
Licence No and Date	0911003067/27/05/2022

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. **12/82-ALC4/2013 dated 19.09.2013** against advance authorization No. **0810123477**

dated 05.08.2013, 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	ACEBUTOLOL Tablets 200 mg([Each film coated tablet contains Acebutolol Hydrochloride Ph.Eur equivalent to Acebutolol 200mg])	1 Number.	1	Acebutolol Hydrochloride Ph.Eur	221.698 mg
2	ACEBUTOLOL Tablets 400 mg([Each film coated tablet contains Acebutolol Hydrochloride Ph.Eur equivalent to Acebutolol 400mg])	1 Number.	2	Acebutolol Hydrochloride Ph.Eur	443.396 mg

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

Case No.	274 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	AARTI DRUGS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001064AM23
RA File Number	03AX04000874 AM23
Licence No and Date	0311015096/30/05/2022

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Sep/202223/8 dated 23.09.2022** against advance authorization No. **0311004037 dated 25.05.2021**, 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.
Ciprofloxacin Hydrochloride	1 kg	1	Ethyl 3 Cyclopropylamino-2(2,4 Dichloro-	1.240 kg

BP/EP/USP (Ciprofloxacin)			5Fluorobenzoyl) Acrylate	
		2	Piperazine Anhydrous	0.390 kg

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

Case No.	275 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ETERNIS FINE CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001065AM23
RA File Number	03AX04000506 AM23
Licence No and Date	0311015097/30/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	276 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	BENZO CHEM INDUSTRIES PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001068AM23
RA File Number	03AX04000845 AM23
Licence No and Date	0311015100/30/05/2022
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	277 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	CONNEX PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001077AM23
RA File Number	26AX04000015 AM23
Licence No and Date	2611000601/30/05/2022
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. **NC/3/MEET/Apr/20223/1 dated 29.04.2022** against advance authorization No. **2611000203 dated 26.07.2021**, 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.
CHLOROMETHYL ISOPROPYL CARBONATE (API)	1 kg	1	METHYLCHLORO FORMATE	0.943 kg

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

Case No.	278 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001061AM23
RA File Number	03AX04000415 AM23
Licence No and Date	0311015092/30/05/2022

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.

Case No.	279 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001063AM23
RA File Number	03AX04000468 AM23
Licence No and Date	0311015094/30/05/2022

Norms Committee Decision:

Deferred for comments of TE.

Case No.	280 / NC/3/MEET/Nov/202223/12
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001081AM23
RA File Number	52AX04000053 AM23
Licence No and Date	5211002556/31/05/2022

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.
PARA ANISIC ACID	100000 kg	1	ParaHydroxy Benzoic Acid	103000 kg

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

Case No.	281 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	CHEMPLAST SANMAR LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001082AM23
RA File Number	04AX04000075 AM23
Licence No and Date	0411003399/31/05/2022

Norms Committee Decision:

Deferred for comments of TE.

Case No.	282 / NC/3/MEET/Nov/202223/12
Case Status	Case Deferred
Party Name	ZENFOLD SUSTAINABLE TECHNOLOGIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ Nov/ 202223/ 12 and 18/11/2022
HQ File Number	HQRNORM APPLY 00001090AM23
RA File Number	09AX04000132 AM23
Licence No and Date	0911003083/31/05/2022

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. **Percentage yield at difference stage of reaction.**

Stoichiometric balance on molar basis to arrive at the quantity of raw material asked for.