



Government of India
Ministry of Commerce and Industry
Department of Commerce

DIRECTORATE GENERAL OF FOREIGN TRADE
(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III

MEETING No. NC/3/MEET/May/202223/4

DATED: 17/06/2022

Please Note

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

Meeting No. NC/3/MEET/May/202223/4 dated 17/06/2022 of Norms Committee - III for the year 2022-23 was held on 17/06/2022 under the Chairmanship of Amiya Chandra, Additional 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	SHAISH KUMAR, Technical Authority	Technical Consultant, DGFT
3	DINESHNARAIN MATHUR, Technical Authority	Technical Consultant, DGFT

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022			
HQ File Number	HQRNORM REVIW00000357AM23			
RA File Number	522404000019 AM17			
Licence No and Date	5210041935/17/06/2016			
Norms Committee Decision:				
The Committee considered the request of firm for review of norms and it was decided to revise adhoc norms as under :				
Export product	Qty.	Sl. No.	Import items	Qty.
1-(3-CHLORO PHENYL) 4-(3-CHLORO PROPYL) PIPERAZINE HCL	1 kg	1	META CHLORO ANILINE	0.88 kg
		2	1,3-BROMO CHLORO PROPANE 99% MIN.	1.045 kg
		3	BIS-(2-CHLORO ETHYL) AMINE HCL	1.16 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	2 / NC/3/MEET/May/202223/4			
Case Status	Case Approved			
Party Name	AMI ORGANICS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022			
HQ File Number	HQRNORM REVIW00000358AM23			
RA File Number	522404000050 AM18			
Licence No and Date	5210042446/04/12/2017			
Norms Committee Decision:				
The Committee considered the request of firm for review of norms and it was decided to revise adhoc norms as under :				
Export product	Qty.	Sl.	Import items	Qty.

		No.		
1-(3-CHLORO PHENYL) 4-(3-CHLORO PROPYL) PIPERAZINE HCL	1 kg	1	META CHLORO ANILINE	0.88 kg
		2	1,3-BROMO CHLORO PROPANE 99% MIN.	1.045 kg

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

Case No.	3 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000359AM23
RA File Number	522404000058 AM18
Licence No and Date	5210042463/22/12/2017

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
1-(3-CHLORO PHENYL) 4-(3-CHLORO PROPYL) PIPERAZINE HCL	1 kg	1	META CHLORO ANILINE	0.88 kg
		2	1,3-BROMO CHLORO PROPANE 99% MIN.	1.045 kg

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

Case No.	4 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000347AM23
RA File Number	522404000085 AM18

Licence No and Date	5210042570/20/03/2018			
Norms Committee Decision:				
The Committee considered the request of firm for review of norms and it was decided to revise adhoc norms as under :				
Export product	Qty.	Sl. No.	Import items	Qty.
TERT- BUTYL 1-PIPERAZINE CARBOXYLATE (1-BOC PIPERAZINE)	1 kg	1	DI- Tert Butyl Dicarbonate	2.00 kg
		2	PIPERAZINE ANHYDROUS	0.80 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	5 / NC/3/MEET/May/202223/4			
Case Status	Case Approved			
Party Name	ATUL LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022			
HQ File Number	018205001846AM19			
RA File Number	082404000030 AM19			
Licence No and Date	0810142955/04/07/2018			
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.
Formulated Aromatic Amine1 (containing 74.7% Aromatic Amine, 11.8% Di Ethyl Toluene Diamine and 13.5% Iso Phoron Diamine)	300000.00 kg	1	Aniline / Aniline Oil	241200.00 kg
		2	Methanol	51600.00 kg
		3	Di Ethyl Toluene Diamine / Ethacure 100 / Lonzacure DETDA 80 / DETDA 80 / DETDA	35400.00 kg

		4	Iso Phoron Diamine / Vestamine IPD / Baxxodur EC 201 / Wanamine IPDA	40500.00 kg
RA concerned may take further necessary action as per above decision of NC.				

Case No.	6 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000196AM23
RA File Number	342404000094 AM19
Licence No and Date	3410044399/08/08/2018
Norms Committee Decision:	
The Committee considered the request of firm for review of norms and it was observed that the yield indicated is 70.17%, which seems to be low. Hence, the Committee decided to call for following information / documents from the firm:	
Production / Consumption data for last two years duly certified by GST Authorities	

Case No.	7 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	NATURAL REMEDIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000342AM23
RA File Number	072404000170 AM19
Licence No and Date	0710113897/25/09/2018
Norms Committee Decision:	
The Committee considered the request of firm for review of norms and it was decided to call for following information / documents from	
(i) Complete specification and COA of import item, indicating impurity profile from foreign supplier. (ii) Production / Consumption data duly certified by GST. (iii) Net weight of export product. (iv) Use of Export Product.	

Case No.	8 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	VARAHI PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001090AM19
RA File Number	NA
Licence No and Date	NA

Norms Committee Decision:

The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I for Advance Authorization No. 6610000013 dated 03.10.2018 having RLA F. No. 662404000004AM19, 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	3-METHYL 4-NITRO BENZOIC ACID	1.28 kg
		2	4-METHYL 2-CYANO BIPHENYL	0.80 kg
		3	POLY PHOSPHORIC ACID	1.49 kg

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

Case No.	9 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000392AM23
RA File Number	039404000496 AM20
Licence No and Date	0310831890/27/09/2019

Norms Committee Decision:

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

Production / Consumption data for last three years duly certified by GST Authorities

Case No.	10 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000393AM23
RA File Number	039404000497 AM20
Licence No and Date	0310831894/27/09/2019
Norms Committee Decision: The Committee considered the request of firm for review of norms and it was decided to call for following information / documents from the firm: Production / Consumption data for last three years duly certified by GST Authorities	

Case No.	11 / NC/3/MEET/May/202223/4			
Case Status	Case Approved			
Party Name	STERILE INDIA PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022			
HQ File Number	018205000719AM20			
RA File Number	052404000377 AM20			
Licence No and Date	0510412070/10/10/2019			
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.	12 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	MENTHA AND ALLIED PRODUCTS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022

and Date	
HQ File Number	018205000763AM20
RA File Number	052404000375 AM20
Licence No and Date	0510412231/23/10/2019
Norms Committee Decision: The Committee considered the request of firm for review of norms and it was decided to call for following information / documents from the firm: (i) Complete composition of Export item No. 2 and 3 indicating percentage of Citrus Aldehyde and Natural Waxes. (ii) Percentage concentration of export.	

Case No.	13 / NC/3/MEET/May/202223/4			
Case Status	Case Approved			
Party Name	ATUL LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022			
HQ File Number	018205000812AM20			
RA File Number	082404000258 AM20			
Licence No and Date	0810146544/13/11/2019			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBI Vol. I as per details given below or as applied by the firm, whichever is less:				
Export product	Qty.	Sl. No.	Import items	Qty.
Formulated Aromatic Amine1 (containing 74.7% Aromatic Amine, 11.8% Di Ethyl Toluene Diamine and 13.5% Iso Phoron Diamine)	300000.00 kg	1	Aniline / Aniline Oil	241200.00 kg
		2	Methanol	51600.00 kg
		3	Di Ethyl Toluene Diamine / Ethacure 100 / Lonzacure DETDA 80 / DETDA 80 / DETDA	35400.00 kg
		4	Iso Phoron Diamine / Vestamine IPD / Baxxodur EC 201 / Wanamine IPDA	40500.00 kg

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

Case No.	14 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	VEKO CARE PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205000821AM20
RA File Number	318304000104 AM20
Licence No and Date	3110067591/15/11/2019

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	Tylox-Gold WSP (Tylosin and Doxycycline Water Soluble Powder)	1 kg	1	Doxycycline Hyclate Grade-BP	0.202 kg
			2	Tylosin Tartrate (VET)	0.101 kg
2	Neodox-Gold WSP (Doxycycline and Neomycin Water Soluble Powder)	1 kg	1	Doxycycline Hyclate Grade-BP	0.101 kg
3	AmpKO-50 (Amprolium Soluble Powder USP 50% W/W)	1 kg	3	Amprolium HCL-USP	0.505 kg

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

Case No.	15 / NC/3/MEET/May/202223/4
Case Status	Case Rejected
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205000828AM20
RA File Number	039404000628 AM20

Licence No and Date	0310832799/15/11/2019
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm still has not furnished its reply. Hence, the Committee decided to reject the case. RA concerned may take further necessary action as per above decision of NC.	

Case No.	16 / NC/3/MEET/May/202223/4													
Case Status	Case Approved													
Party Name	RENOWN PHARMACEUTICALS PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022													
HQ File Number	018205001018AM20													
RA File Number	342404000326 AM20													
Licence No and Date	3410045792/17/01/2020													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>SOFT GELATIN CAPSULES (ITC (HS) CODE 30045090 / 30045039) (NET CONTENT : 1) GELATIN 175 BLOOM 5-15 MESH : 20395.922 KILOGRAM)</td><td>72325965 Number</td><td>1</td><td>GELATIN 175 BLOOM 5-15 MESH</td><td>22436 kg</td></tr></table>					Export product	Qty.	Sl. No.	Import items	Qty.	SOFT GELATIN CAPSULES (ITC (HS) CODE 30045090 / 30045039) (NET CONTENT : 1) GELATIN 175 BLOOM 5-15 MESH : 20395.922 KILOGRAM)	72325965 Number	1	GELATIN 175 BLOOM 5-15 MESH	22436 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
SOFT GELATIN CAPSULES (ITC (HS) CODE 30045090 / 30045039) (NET CONTENT : 1) GELATIN 175 BLOOM 5-15 MESH : 20395.922 KILOGRAM)	72325965 Number	1	GELATIN 175 BLOOM 5-15 MESH	22436 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	17 / NC/3/MEET/May/202223/4			
Case Status	Case Deferred			
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022			
HQ File Number	018205001022AM20			
RA File Number	052404000669 AM20			
Licence No and	0510413373/17/01/2020			

Date	
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that inspite of two deficiency letters; the information given by the firm is incomplete. The yields now given are low and do not match with reaction-sequencing. Technical specification of main raw materials also not given. Hence, the Committee decided to call firm for attending Personal Hearing before Norms Committee to explain its case.	

Case No.	18 / NC/3/MEET/May/202223/4													
Case Status	Case Approved													
Party Name	MAGNOLIA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022													
HQ File Number	018205001551AM21													
RA File Number	039504001071 AM20													
Licence No and Date	0310834718/07/02/2020													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Feb/202122/14 dated 21.02.2022 against advance authorization No. 0311004164 dt. 31.05.2021 , 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:														
<table><tr><td>Export Product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>5-(1H-Pyrrol-1-yl)-2-Mercaptobenzimidazole</td><td>1 kg</td><td>1</td><td>2-Mercapto-5-Methoxy Benzimidazole</td><td>0.898 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import items	Qty.	5-(1H-Pyrrol-1-yl)-2-Mercaptobenzimidazole	1 kg	1	2-Mercapto-5-Methoxy Benzimidazole	0.898 kg
Export Product	Qty.	Sl. No.	Import items	Qty.										
5-(1H-Pyrrol-1-yl)-2-Mercaptobenzimidazole	1 kg	1	2-Mercapto-5-Methoxy Benzimidazole	0.898 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	19 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001599AM21
RA File Number	052404000742 AM20
Licence No and Date	0510413763/02/03/2020
Norms Committee Decision:	

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

Export product	Qty.	Sl. No.	Import items	Qty.
VALPROIC ACID	1 kg	1	DIETHYL MALONATE	1.42 kg
		2	N-PROPYL BROMIDE	2.186 kg
		3	SODIUM HYDROXIDE FLAKES	0.88 kg
		4	TETRA BUTYL AMMONIUM BROMIDE	0.100 kg
		5	SULPHURIC ACID	Not an importable item

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

Case No.	20 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	MANGALAM ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001129AM20
RA File Number	039504001078 AM20
Licence No and Date	0310835280/06/03/2020

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
ISOBORNYL ACETATE	50000 kg	1	GUM TURPENTINE OIL	47645 kg

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

Case No.	21 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	YASH RASAYAN & CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001142AM20
RA File Number	342404000343 AM20
Licence No and Date	3410045953/12/03/2020

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
METHYL 2-METHOXY SULFAMOYL BENZOATE (MSMB)	5 60000.00 kg	1	METHYL SALICYLATE	60000.00 kg
		2	DIMETHYL FORMAMIDE	106800.00 kg

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

Case No.	22 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001136AM20
RA File Number	052404000749 AM20
Licence No and Date	0510413850/12/03/2020

Norms Committee Decision:

The Committee considered the case as per agenda and it was observed that inspite of two deficiency letters; the information given by the firm is incomplete. The yields now given are low and do not match with reaction-sequencing. Technical specification of main raw materials also not given. Hence, the Committee decided to call firm for attending **Personal Hearing** before Norms Committee to explain its case.

Case No.	23 / NC/3/MEET/May/202223/4			
Case Status	Case Approved			
Party Name	YASH RASAYAN & CHEMICALS			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022			
HQ File Number	018205001143AM20			
RA File Number	342404000389 AM20			
Licence No and Date	3410045957/13/03/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBI Vol. I as per details given below or as applied by the firm, whichever is less:				

Case No.	24 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	RECKITT BENCKISER HEALTHCARE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001264AM21
RA File Number	052404000025 AM21
Licence No and Date	0510414108/06/05/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the norms for subject Advance Authorization have already been ratified by NC-3 in its Meeting No. NC/3/MEET/Jan/202021/4 dated 12.02.2021 .	
In view of above, the Committee decided to withdraw the case.	

Case No.	25 / NC/3/MEET/May/202223/4			
Case Status	Case Approved			
Party Name	VEKO CARE PRIVATE LIMITED			

Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022				
HQ File Number	018205001314AM21				
RA File Number	318304000009 AM21				
Licence No and Date	3110067742/21/05/2020				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBI 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	TYLODOX GOLD POWDER 1Kg Jar Tylosin & Doxycycline Water Soluble Powder	1 Number	1	DOXYCYCLINE HYCLATE DOXYCYCLINE HYCLATE GRADE BP	202 grams
			2	TYLOSIN TARTRATE TYLOSIN TARTRATE VET IP/EP/BP	101 grams
2	TYLODOX GOLD POWDER 100 GMS Sachet Tylosin & Doxycycline Water Soluble Powder	1 Number	1	DOXYCYCLINE HYCLATE DOXYCYCLINE HYCLATE GRADE BP	20.20 grams
			2	TYLOSIN TARTRATE TYLOSIN TARTRATE VET IP/EP/BP	10.10 grams
3	NEODOX GOLD POWDER 1KG Jar Neomycin & Doxycycline Soluble Powder	1 Number	1	DOXYCYCLINE HYCLATE DOXYCYCLINE HYCLATE GRADE BP	101.00 grams
4	NEODOX GOLD POWDER 100GMS Sachet Neomycin & Doxycycline Soluble Powder	1 Number	1	DOXYCYCLINE HYCLATE DOXYCYCLINE HYCLATE GRADE BP	10.10 grams
RA concerned may take further necessary action as per above decision of NC.					

Case No.	26 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SYNNAT PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000385AM23
RA File Number	022404000012 AM21

Licence No and Date	0210209889/29/05/2020
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. COA of import item from foreign supplier for the relevant import. Past Production / Consumption data for last three years duly certified by Central Taxes & GST Authorities.	

Case No.	27 / NC/3/MEET/May/202223/4
Case Status	Case Rejected
Party Name	KOPRAN RESEARCH LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001382AM21
RA File Number	039404000156 AM21
Licence No and Date	0310836662/15/06/2020
Norms Committee Decision: The Committee considered the case as per agenda and reply of firm and it was observed that the firm has not given any technical details in its reply. In view of above, the Committee decided to reject the case.	

Case No.	28 / NC/3/MEET/May/202223/4				
Case Status	Case Approved				
Party Name	MAKCUR LABORATORIES LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022				
HQ File Number	018205001388AM21				
RA File Number	082404000062 AM21				
Licence No and Date	0810147963/17/06/2020				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:					
Export product		Qty.	Sl. No.	Import items	Qty.

CEFABACT INJECTION 1 gm (NO SWFI but 20ml vial) (Individual Cartoon Packing)(NET CONTENTS OF BULK DRUG SHOULD NOT BE LESS THAN 250 KGS IN THE RESULTANT PRODUCT AND SHOULD BE SHOWN IN EXPORT DOCUMENTS.)	1 Number	1	CEFOTAXIME SODIUM STERILE USP - THIS AUTHORISATION ISSUED AS PER POLICY CIRCULAR No.9	1.079 gram
RA concerned may take further necessary action as per above decision of NC				

Case No.	29 / NC/3/MEET/May/202223/4																			
Case Status	Case Approved																			
Party Name	YASHO INDUSTRIES LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022																			
HQ File Number	018205001426AM21																			
RA File Number	039504000182 AM21																			
Licence No and Date	0310836907/26/06/2020																			
Norms Committee Decision:																				
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. 7/82-ALC4/2020 dated 04.12.2020 against advance authorization No. 0310825514 dt. 07.12.2018 , 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:																				
<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">YANTQ 3030 B (30% SOLUTION OF TERTIARY BUTYL HYDROQUINONE) in Propylene Glycol</td><td rowspan="3">1 kg</td><td>1</td><td>HYDROQUINONE</td><td>0.423 kg</td></tr><tr><td>2</td><td>TERTIARY BUTANOL</td><td>0.312 kg</td></tr><tr><td>3</td><td>PROPYLENE GLYCOL</td><td>0.700 kg</td></tr></table>					Export Product	Qty.	Sl. No.	Import items	Qty.	YANTQ 3030 B (30% SOLUTION OF TERTIARY BUTYL HYDROQUINONE) in Propylene Glycol	1 kg	1	HYDROQUINONE	0.423 kg	2	TERTIARY BUTANOL	0.312 kg	3	PROPYLENE GLYCOL	0.700 kg
Export Product	Qty.	Sl. No.	Import items	Qty.																
YANTQ 3030 B (30% SOLUTION OF TERTIARY BUTYL HYDROQUINONE) in Propylene Glycol	1 kg	1	HYDROQUINONE	0.423 kg																
		2	TERTIARY BUTANOL	0.312 kg																
		3	PROPYLENE GLYCOL	0.700 kg																
RA concerned may take further necessary action as per above decision of NC.																				

Case No.	30 / NC/3/MEET/May/202223/4
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Case Status	Case Deferred
Party Name	SYNNAT PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000388AM23
RA File Number	022404000050 AM21
Licence No and Date	0210210010/27/07/2020
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. COA of import item from foreign supplier for the relevant import. Past Production / Consumption data for last three years duly certified by Central Taxes & GST Authorities.	

Case No.	31 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	AMINES AND PLASTICIZERS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001625AM21
RA File Number	039404000370 AM21
Licence No and Date	0310838163/08/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Percentage yield of reaction.	

Case No.	32 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	VISWAAT CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001627AM21
RA File Number	039504000327 AM21
Licence No and Date	0310838181/09/09/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP	

Vol. I as per details given below or as applied by the firm, whichever is less:

Export product	Qty.	Sl. No.	Import items	Qty.
VICASOL MV 01 [DIETHANOL ISOPROPANOL AMINE] DEIPA	1 kg	1	DIETHANOL AMINE [DEA]	0.617 kg
		2	PROPYLENE OXIDE	0.383 kg

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

Case No.	33 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	VIBRANT PHARMACHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001663AM21
RA File Number	072404000163 AM21
Licence No and Date	0710117014/15/09/2020

Norms Committee Decision:

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

- i. **Complete and balanced chemical reactions with molecular of each reactant, molar requirement of each import item and its justification.**
- ii. **Percentage yield on molar basis.**

Case No.	34 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	GLENMARK LIFE SCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000405AM23
RA File Number	039404000430 AM21
Licence No and Date	0310838379/21/09/2020

Norms Committee Decision:

The Committee considered the request of firm for review of norms and as per the details now furnished, it was decided

to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
PERINDOPRIL ERBUMINE (PERINDOPRIL ARGININE)	1 kg	1	S-(-)-INDOLINE-2-CARBOXYLIC ACID	Not recommended
		2	L-NORVALINE	Not recommended
		3	ACETONITRILE	3.90 kg
		4	N,N-CARBONYLDIIMIDAZOLE	0.64 kg
		5	(S)-2-CARBOXY OCTAHYDROINDOLE	0.60 kg
		6	N-[(S)-ETHOXYCARBONYL -1-BUTYL)-(S)-ALANINE	0.85 kg
		7	METHYLENE CHLORIDE (MDC)	6.15 kg
		8	SODIUM PYRUVATE	Not recommended
		9	METHANOL	Not required in the process

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

Case No.	35 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	SIDMAK LABORATORIES (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001682AM21
RA File Number	522404000047 AM21
Licence No and Date	5210043542/22/09/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:	

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Minocycline Hydrochloride Capsules / Tablets 50 mg (Each Capsule/Tablet contains Minocycline 50mg.(Equivalent to Minocycline Hydrochloride 53.98mg.) Pharmaceutical Formulations / Standard Grade) (Equivalent to 32.388Kg of bulk drug))	1 Number	1	Minocycline Hydrochloride	55.06 mg
2	Minocycline Hydrochloride Capsules / Tablets 100 mg (Each Capsule/Tablet contains Minocycline 100mg.(Equivalent to Minocycline Hydrochloride 107.97mg.) Pharmaceutical Formulations / Standard Grade) (Equivalent to 712.602Kg of bulk drug) Total Bulk Drug Qty. 744.990Kg.)	1 Number	1	Minocycline Hydrochloride	110.12 mg

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

Case No.	36 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001688AM21
RA File Number	052404000308 AM21
Licence No and Date	0510415295/23/09/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Feb/202122/14 dated 21.02.2022** against advance authorization No. **0510414600 dt. 10.07.2020**, 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:

Sl. No.	Export Product	Qty.	Sl. No.	Import items	Qty.
1	ACETAZOLAMIDE TABLETS, 125 MG	1 Number	1	ACETAZOLAMIDE USP	127.50 mg
2	ACETAZOLAMIDE TABLETS, 250 MG	1 Number	2	ACETAZOLAMIDE USP	255.00 mg

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

Case No.	37 / NC/3/MEET/May/202223/4
Case Status	Case Rejected
Party Name	SRI CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000336AM23
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 observed that the firm has not furnished any technical details in support of its request

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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.	38 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	BELCHEM INDUSTRIES (INDIA) PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001738AM21
RA File Number	039404000504 AM21
Licence No and Date	0310838842/13/10/2020

Norms Committee Decision:

The Committee considered the case as per and reply received from the firm on DGFT Back Office Portal and it was observed that the reply furnished by the firm is not readable. Hence, it was decided to again call for following

information/documents from the firm:

i. Copy of 4.07 application having copy of Advance Authorization alongwith complete technical details as per Annexure to Appendix 4E.

(ii) Stoichiometric balance, molecular weight, percentage yield at every stage of reaction.

Case No.	39 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SYNNAT PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001771AM21
RA File Number	022404000094 AM21
Licence No and Date	0210210167/20/10/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. COA of import item from foreign supplier. ii. Past Production / Consumption data duly certified by GST Authorities.	

Case No.	40 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	INNOVARE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001770AM21
RA File Number	262404000018 AM21
Licence No and Date	2610012921/20/10/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Please specify export item with structure and molecular weight.	

Case No.	41 / NC/3/MEET/May/202223/4
Case Status	Case Approved

Party Name	MAHIMA LIFESCIENCES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022													
HQ File Number	018205001793AM21													
RA File Number	052404000372 AM21													
Licence No and Date	0510415667/28/10/2020													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:														
<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>PREDNISOLONE MICRONISED (Partich size less than 30 micron)</td><td>1 kg</td><td>1</td><td>PREDNISOLONE (Partich size 99% < 120 µm)</td><td>1 kg</td></tr> </tbody> </table>					Export product	Qty.	Sl. No.	Import items	Qty.	PREDNISOLONE MICRONISED (Partich size less than 30 micron)	1 kg	1	PREDNISOLONE (Partich size 99% < 120 µm)	1 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
PREDNISOLONE MICRONISED (Partich size less than 30 micron)	1 kg	1	PREDNISOLONE (Partich size 99% < 120 µm)	1 kg										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	42 / NC/3/MEET/May/202223/4																			
Case Status	Case Approved																			
Party Name	ALEOR DERMACEUTICALS LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022																			
HQ File Number	018205001801AM21																			
RA File Number	342404000205 AM21																			
Licence No and Date	3410046497/28/10/2020																			
Norms Committee Decision:																				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:																				
<table border="1"> <thead> <tr> <th>Sl. No.</th><th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr> </thead> <tbody> <tr> <td>1</td><td>Clobetasol Propionate Cream USP 0.05% 15 gm (net content of active ingredients 225.00 gm.)</td><td>30000 Number</td><td rowspan="2">1</td><td rowspan="2">Clobetasol Propionate USP (Micronized)</td><td rowspan="2">5000.180 gram</td></tr> <tr> <td>2</td><td>Clobetasol Propionate Cream USP 0.05% 30 gm</td><td>7009</td></tr> </tbody> </table>						Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.	1	Clobetasol Propionate Cream USP 0.05% 15 gm (net content of active ingredients 225.00 gm.)	30000 Number	1	Clobetasol Propionate USP (Micronized)	5000.180 gram	2	Clobetasol Propionate Cream USP 0.05% 30 gm	7009
Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.															
1	Clobetasol Propionate Cream USP 0.05% 15 gm (net content of active ingredients 225.00 gm.)	30000 Number	1	Clobetasol Propionate USP (Micronized)	5000.180 gram															
2	Clobetasol Propionate Cream USP 0.05% 30 gm	7009																		

	(net content of active ingredients 105.135 gm.)	Number			
3	Clobetasol Propionate Cream USP 0.05% 45 gm (net content of active ingredients 191.25 gm.)	8500 Number			
4	Clobetasol Propionate Cream USP 0.05% 60 gm (net content of active ingredients 1200.00 gm.)	40000 Number			
5	Clobetasol Propionate Topical Solution USP 0.05% 25ml net content of active ingredients 625.00 gm.)	50000 Number			
6	Clobetasol Propionate Topical Solution USP 0.05% 50 ml net content of active ingredients 900.00 gm.)	36000 Number			
7	Clobetasol Propionate Topical Shampoo, 0.05% 118 ml (net content of active ingredients 1166.253 gm.)	19767 Number			
8	Clobetasol Propionate Spray, 0.05% - 59 ml (net content of active ingredients 177.00 gm.)	6000 Number			
9	Clobetasol Propionate Spray, 0.05% - 125 ml net content of active ingredients 312.500 gm.)	5000 Number			

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

Case No.	43 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001804AM21
RA File Number	092404000388 AM21
Licence No and Date	0910069417/29/10/2020
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	

(i) Percentage yield on molar basis for each step of manufacturing process.**Justification for requirement of import item No. 2 to 6 with reaction details.**

Case No.	44 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	OPTIMUS DRUGS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001805AM21
RA File Number	092404000389 AM21
Licence No and Date	0910069418/29/10/2020

Norms Committee Decision:

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

(i) Percentage yield on molar basis for each step of manufacturing process.**Justification for requirement of import item No. 2 to 6 with reaction details**

Case No.	45 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	DEEPAK PHENOLICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000133AM23
RA File Number	342404000202 AM21
Licence No and Date	3410046526/05/11/2020

Norms Committee Decision:

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	PHENOL	4859 MT	1	CUMENE	4286 MT
2	ACETONE	2964 MT	2	CUMENE	2614 MT

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

Case No.	46 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001835AM21
RA File Number	342404000204 AM21
Licence No and Date	3410046524/05/11/2020

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Jan/202021/4 dated 12.02.2021** against advance authorization No. **3410045200 dt. 10.06.2019**, 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
Gamma Nonalactone or Aldehyde C18	1 kg	1	Hexyl Alcohol or N-Hexanol	0.90 kg
		2	Acrylic Acid	0.66 kg
		3	Di-tert Butyl Peroxide	0.229 kg

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

Case No.	47 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SYNNAT PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000390AM23
RA File Number	022404000099 AM21
Licence No and Date	0210210204/09/11/2020

Norms Committee Decision:

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

- i. COA of import item from foreign supplier for the relevant import.**

Past Production / Consumption data for last three years duly certified by Central Taxes & GST Authorities.

Case No.	48 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	ALEOR DERMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	018205001853AM21
RA File Number	342404000223 AM21
Licence No and Date	3410046549/13/11/2020

Norms Committee Decision:

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

- i. COA of import item Nystatin USP from foreign supplier.**

Justification for arriving at net content in export products and wastage applied

Case No.	49 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000231AM23
RA File Number	31AA04005358 AM21
Licence No and Date	3111000104/21/01/2021

Norms Committee Decision:

The Committee considered the request of firm for review of norms and it was observed that due to oversight, earlier the quantity of import item No. 1 - Mono Ethanol Amine, was reduced to 0.184 kg. Hence, the Committee decided to revise adhoc norms as under:

Export product	Qty.	Sl. No.	Import items	Qty.
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DIETHYLENETRIAMINE (ORGANIC CHEMICAL)	1 kg	1	MONO ETHANOL AMINE	1.184 kg
		2	AMMONIA ANHYDROUS	0.165 kg

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

Case No.	50 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000228AM23
RA File Number	31AA04006051 AM21
Licence No and Date	3111000148/09/02/2021
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. Stoichiometric balance on the basis of molecular weight and percentage yield of reaction. If Ammonia Anhydrous is procured from indigenous source, then why it is indicated in the licence	

Case No.	51 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00000226AM23
RA File Number	31AA04006435 AM21
Licence No and Date	3111000179/08/03/2021
Norms Committee Decision: The Committee considered the request of firm for enhancement of norms and it was decided to call for following information / documents from the firm: i. Stoichiometric balance on the basis of molecular weight and percentage yield of reaction to arrive at the quantity of raw material asked for.	

Case No.	52 / NC/3/MEET/May/202223/4										
Case Status	Case Approved										
Party Name	RENOWN PHARMACEUTICALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022										
HQ File Number	HQRNORM APPLY 00117718AM21										
RA File Number	34AA04003342 AM21										
Licence No and Date	3411000346/31/03/2021										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:											
<table><tr><th>Export product</th><th>Qty.</th><th>Sl. No.</th><th>Import items</th><th>Qty.</th></tr><tr><td>Soft Gelatin Capsule Shells (330 mg to 370 mg) (ITC(HS) Code Number 30045090/30045039/30049090/30049099) (Net Content: Gelatin 175 Bloom 5-15 Mesh:25760.00 KGS)</td><td>62250420</td><td>1</td><td>Gelatin 175 Bloom 5-15 Mesh</td><td>25295 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Soft Gelatin Capsule Shells (330 mg to 370 mg) (ITC(HS) Code Number 30045090/30045039/30049090/30049099) (Net Content: Gelatin 175 Bloom 5-15 Mesh:25760.00 KGS)	62250420	1	Gelatin 175 Bloom 5-15 Mesh	25295 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
Soft Gelatin Capsule Shells (330 mg to 370 mg) (ITC(HS) Code Number 30045090/30045039/30049090/30049099) (Net Content: Gelatin 175 Bloom 5-15 Mesh:25760.00 KGS)	62250420	1	Gelatin 175 Bloom 5-15 Mesh	25295 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	53 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00117194AM21
RA File Number	09AA04006983 AM21
Licence No and Date	0911000644/31/03/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Copy of DML.	
ii. Copy of Master Batch Formula for export item.	

Case No.	54 / NC/3/MEET/May/202223/4			
Case Status	Case Approved			

Party Name	SENTISS PHARMA PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022													
HQ File Number	HQRNORM APPLY 00117330AM21													
RA File Number	05AA04043417 AM21													
Licence No and Date	0511002009/31/03/2021													
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less: <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>Brimonidine Tartrate 0.1 Percent Eye Drops Solution 5ml Santabrim</td> <td>166667 Vials</td> <td>1</td> <td>Brimonidine Tartrate USP</td> <td>0.85 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.	Brimonidine Tartrate 0.1 Percent Eye Drops Solution 5ml Santabrim	166667 Vials	1	Brimonidine Tartrate USP	0.85 kg
Export product	Qty.	Sl. No.	Import items	Qty.										
Brimonidine Tartrate 0.1 Percent Eye Drops Solution 5ml Santabrim	166667 Vials	1	Brimonidine Tartrate USP	0.85 kg										

Case No.	55 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	GRANULES INDIA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00117574AM21
RA File Number	09AA04005560 AM21
Licence No and Date	0911000476/31/03/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Copy of DML. ii. Copy of Master Batch Formula.	

Case No.	56 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	VIBRANT PHARMACHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022

HQ File Number	HQRNORM APPLY 00000295AM22
RA File Number	07AA04011201 AM21
Licence No and Date	0711000825/01/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Complete and balanced chemical reactions with molecular of each reactant, molar requirement of each import item and its justification. ii. Percentage yield on molar basis.	

Case No.	57 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00000680AM22
RA File Number	30AA04006198 AM21
Licence No and Date	3011000463/01/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Complete chemistry, molecular weight and percentage yield on molar basis may be furnished in line with Annexure to Appendix 4E.	

Case No.	58 / NC/3/MEET/May/202223/4
Case Status	Case Rejected
Party Name	FRESENIUS KABI ONCOLOGY LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00000740AM22
RA File Number	05AA04041798 AM21
Licence No and Date	0511001982/01/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the import item is disproportionately high with respect to export and for that the firm has not given any technical justification. 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.	59 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00004824AM22
RA File Number	05AA04000952 AM22
Licence No and Date	0511002092/06/04/2021

Norms Committee Decision:

The Committee considered the case as per agenda and it was observed that inspite of two deficiency letters; the information given by the firm is incomplete. The yields now given are low and do not match with reaction-sequencing. Technical specification of main raw materials also not given. Hence, the Committee decided to call firm for attending **Personal Hearing** before Norms Committee to explain its case.

Case No.	60 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	BAROQUE PHARMACEUTICALS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00007930AM22
RA File Number	08AA04012530 AM21
Licence No and Date	0811001119/09/04/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
GLUCOSAMINE SULFATE 500MG & CHONDROITIN SULFATE 400MG TABLET(GLUCOSAMINE SULFATE 500MG & CHONDROITIN SULFATE 400MG TABLET (EACH TABLET CONTAINING GLUCOSAMINE SULFATE SODIUM CHLORIDE 628 MG AND CHONDROITIN SULPHATE SODIUM 431 MG))	10,000,000 Number	1	GLUCOSAMINE SULFATE SODIUM CHLORIDE	6405.6 kg
		2	CHONDROITIN SULFATE SODIUM	4396.2 kg

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

Case No.	61 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	NASENSE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00019535AM22
RA File Number	09AA04000085 AM22
Licence No and Date	0911000683/15/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Percentage yield of reaction at every step. ii. Copy of earlier norms approved.	

Case No.	62 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00020260AM22
RA File Number	34AA04000021 AM22
Licence No and Date	3411000455/16/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Justification for 10% wastage as indicated in Appendix 4E. ii. Details of indigenous input, i.e. Vegetable Fat. iii. COA of each export item giving net content of each input.	

Case No.	63 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022

and Date	
HQ File Number	HQRNORM APPLY 00021691AM22
RA File Number	05AA04002818 AM22
Licence No and Date	0511002233/19/04/2021

Norms Committee Decision:

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

Export product	Qty.	Sl. No.	Import items	Qty.
VALPROIC ACID	1 kg	1	DIETHYL MALONATE	1.42 kg
		2	N-PROPYL BROMIDE	2.186 kg
		3	SODIUM HYDROXIDE FLAKES	0.88 kg
		4	TETRA BUTYL AMMONIUM BROMIDE	0.100 kg
		5	SULPHURIC ACID	Not an importable item

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

Case No.	64 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00023689AM22
RA File Number	07AA04002023 AM22
Licence No and Date	0711000922/21/04/2021

Norms Committee Decision:

Deferred for comments of TE.

Case No.	65 / NC/3/MEET/May/202223/4
Case Status	Case Deferred

Party Name	GARUDA CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00024406AM22
RA File Number	03AA04031910 AM21
Licence No and Date	0311003270/22/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights alongwith 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.	66 / NC/3/MEET/May/202223/4										
Case Status	Case Approved										
Party Name	ALKALOIDS CORPORATION										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022										
HQ File Number	HQRNORM APPLY 00025210AM22										
RA File Number	02AA04001824 AM22										
Licence No and Date	0211000589/23/04/2021										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from earlier decision for same export product / import item in Meeting No. NC/3/MEET/Jan/202122/13 dated 21.01.2022 against advance authorization No. 0210207932 dt. 02.11.2017 , 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: :											
<table><tr><td>Export product</td><td>Qty.</td><td>Sl. No.</td><td>Import items</td><td>Qty.</td></tr><tr><td>Digoxin</td><td>1 kg</td><td>1</td><td>Digitalis Lanata Leaves (Dried) (Digoxin content NMT 0.3%)</td><td>436.525 kg</td></tr></table>		Export product	Qty.	Sl. No.	Import items	Qty.	Digoxin	1 kg	1	Digitalis Lanata Leaves (Dried) (Digoxin content NMT 0.3%)	436.525 kg
Export product	Qty.	Sl. No.	Import items	Qty.							
Digoxin	1 kg	1	Digitalis Lanata Leaves (Dried) (Digoxin content NMT 0.3%)	436.525 kg							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	67 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00026336AM22
RA File Number	09AA04001513 AM22
Licence No and Date	0911000730/26/04/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Oct/202122/10 dated 12.11.2021** against advance authorization No. **0311004164 dt. 31.05.2021**, 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.
Tolvaptan(pharmaceutical product)	1 kg	1	7-Chloro-1,2,3,4-tetrahydro-5H-1-Benzazepin-5-one	0.96 kg
		2	4-Nitro-2-methyl Benzoic Acid	1.00 kg

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

Case No.	68 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	GLOBAL CALCIUM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00027780AM22
RA File Number	07AA04000758 AM22
Licence No and Date	0711000991/27/04/2021

Norms Committee Decision:

The Committee considered the case as per agenda and 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 alongwith**

stage wise percentage yields on molar basis.

iii. Complete technical details as per Annexure to Appendix 4E for chemical products.

iv. Stoichiometric balance between import and export on molar basis.

v. Production / Consumption data duly certified by GST for the year 2018-19, 2019-20.

vi. Justification for 27.32% and 41.86% wastage for Glycerine and Magnesium Hydrochloride.

Case No.	69 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00027802AM22
RA File Number	07AA04002553 AM22
Licence No and Date	0711000992/27/04/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	70 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00027804AM22
RA File Number	07AA04002549 AM22
Licence No and Date	0711000993/27/04/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	71 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	R.L.FINE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00028506AM22
RA File Number	07AA04002556 AM22
Licence No and Date	0711001000/28/04/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	72 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	ZYDUS LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00028425AM22
RA File Number	08AA04001824 AM22
Licence No and Date	0811001352/28/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the norms for subject Advance Authorization have already been ratified by NC-3 in its Meeting No. NC/3/MEET/Jun/202122/2 dated 02/07/2021. In view of above, the Committee decided to withdraw the case.	

Case No.	73 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	BHAGWATI INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00029214AM22
RA File Number	08AA04001833 AM22
Licence No and Date	0811001364/29/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Step wise manufacturing process. Complete chemical reactions with molecular and structural formula and molecular weights alongwith 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. Production / Consumption data duly certified by GST for the year 2018-19, 2019-20. End use of export product.	

Case No.	74 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00029824AM22
RA File Number	03AA04003827 AM22

Licence No and Date	0311003447/30/04/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name. ii. Details of Packaging Material may be furnished. iii. Copy of Master Batch Formula for all export items indicating net content of inputs in each export.	

Case No.	75 / NC/3/MEET/May/202223/4			
Case Status	Case Approved			
Party Name	KALKI HEALTHCARE PRIVATE LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022			
HQ File Number	HQRNORM APPLY 00031354AM22			
RA File Number	34AA04000999 AM22			
Licence No and Date	3411000521/03/05/2021			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to ratify adhoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:				

Case No.	76 / NC/3/MEET/May/202223/4				
Case Status	Case Deferred				
Party Name	CLARIANT INDIA LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022				
HQ File Number	HQRNORM APPLY 00032203AM22				
RA File Number	03AA04009823 AM22				
Licence No and	0311003530/04/05/2021				

Date	
Norms Committee Decision: The Committee considered the case as per agenda and reply furnished by the firm. It was observed that the reply furnished by the firm was not proper. Hence, it was decided to again call for following information / documents from the firm: (i) Percentage yield at every stage of reaction. (ii) Justification for quantity of import asked on the basis of Stoichiometric balance reactions	

Case No.	77 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	GRAMEN BOTANICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00032213AM22
RA File Number	05AA04005603 AM22
Licence No and Date	0511002405/04/05/2021

Norms Committee Decision:

The Committee considered the case as per agenda and 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.
BERBERINE HYDROCHLORIDE (97 PERCENT)	1 kg	1	BERBERIS ARISTATA EXTRACT (Assay 90% +/- 1%)	1.00 kg

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

Case No.	78 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00032713AM22
RA File Number	05AA04009888 AM22
Licence No and Date	0511002414/04/05/2021

Norms Committee Decision:

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

- i. Complete and balanced chemical reactions with molecular weight and percentage yield on molar basis.**
- ii. Stepwise material balance.**
- iii. Requirement and recovery of solvent of each step.**
- iv. Past Production / Consumption data for Buprenorphine HCL Bulk Drug.**
- v. Wastage applied on tablets from Bulk Drug.**

Case No.	79 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00033515AM22
RA File Number	05AA04007697 AM22
Licence No and Date	0511002442/05/05/2021

Norms Committee Decision:

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

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

Case No.	80 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SUDEEP PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00033649AM22
RA File Number	34AA04000874 AM22
Licence No and Date	3411000530/05/05/2021

Norms Committee Decision:

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

- i. Step wise manufacturing process.
- ii. Complete chemical reactions with molecular and structural formula and molecular weights alongwith stage wise percentage yields on molar basis.
- iii. Complete technical details as per Annexure to Appendix 4E for chemical products.
- iv. Stoichiometric balance between import and export on molar basis.
- v. Details of indigenous input with quantity.
- vi. Production / Consumption data duly certified by GST for the year 2018-19, 2019-20 and 2020-21.
- vii. Justification for wastage at each stage of reaction.

Case No.	81 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00033514AM22
RA File Number	03AA04009664 AM22
Licence No and Date	0311003582/05/05/2021

Norms Committee Decision:

The Committee considered the case as per agenda and 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:

Sl. No.	Export Product	Qty.
1	FLUCORT N SKIN CREAM 0.025percent (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 1.210 Kgs.)	322660 Number
2	FLUCORT SKIN CREAM 0.025percent (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 1.210 Kgs.)	322660 Number
3	FLUCORT SKIN CREAM 0.025percent (Pack Size 10 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.605 Kgs.)	242000 Number
4	FLUCORT SKIN CREAM 0.025percent (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 1.210 Kgs.)	968000 Number
5	FLUOCINOLONE CREAM (TDR) ET 0.025percent (Pack Size 10 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	96800 Number
6	CYNOZET CREAM 0.025percent (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	193600 Number

7	CYNOZET CREAM 0.025percent (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	64532 Number
8	SUPRICORT CREAM 0.025percent (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.726 Kgs.)	580800 Number
9	SUPRICORT CREAM 0.025percent (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.726 Kgs.)	193596 Number
10	SUPRICORT CREAM 0.025percent (Pack Size 250 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	3873 Number
11	SUPRICORT N CREAM 0.025percent (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	193600 Number
12	SUPRICORT N CREAM 0.025percent (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.)	64532 Number
13	Flucort C Cream 0.01percent (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.095 Kgs)	63332 Number
14	FLUCORT C OINTMENT 0.025percent (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.605 Kgs.)	161330 Number
15	GLENCORT GEL 0.025percent (Pack Size 5 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.452 Kgs.)	361600 Number
16	GLENCORT GEL 0.025percent (Pack Size 30 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.484 Kgs.)	64535 Number
17	FLUCORT MZ SKIN OINTMENT 0.01percent (Pack Size 15 gms) (Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.145 Kgs.)	96798 Number

Sl. No.	Import Items	Qty
1	FLUOCINOLONE ACETONIDE BP	9.10 kg

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

Case No.	82 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	ALTA LABORATORIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00033839AM22
RA File Number	03AA04011093 AM22
Licence No and Date	0311003601/06/05/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Mar/202122/16 dated 08.04.2022** against advance authorization No.**0311008559 dt. 15.11.2021**, 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.
METHYL PARABEN	1 kg	1	Para Hydroxy Benzoic Acid	0.97 kg
		2	Methanol	0.50 kg

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

Case No.	83 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00036355AM22
RA File Number	03AA04007493 AM22
Licence No and Date	0311003675/09/05/2021

Norms Committee Decision:

Deferred for comments of TE.

Case No.	84 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	PORUS LABORATORIES PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022

and Date	
HQ File Number	HQRNORM APPLY 00036920AM22
RA File Number	09AA04002104 AM22
Licence No and Date	0911000798/10/05/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Complete technical details as per Appendix 4E. ii. End-use of Export item. Production / Consumption data duly certified by GST Authorities	

Case No.	85 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	MACLEODS PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00038818AM22
RA File Number	03AA04005126 AM22
Licence No and Date	0311003736/12/05/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Five import items are shown in the licence, whereas only 2 inputs have been shown imported under Appendix 4E. Please clarify it. ii. Consumption-coefficient of each imported input for API. iii. Wastage claimed on API to manufacture tablets.	

Case No.	86 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	EAST AFRICAN INDIA OVERSEAS
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00039055AM22
RA File Number	05AA04009662 AM22
Licence No and Date	0511002560/12/05/2021
Norms Committee Decision:	

The Committee considered the case as per agenda and it was observed that each injection is having potency of 25,000 units. However, the firm has applied for total import quantity of 900 units against export of 33,783 injections. No norms can be proposed in its present form.

In view of above discrepancy, it was decided to call firm for attending **Personal Hearing** before Norms Committee alongwith relevant documents to explain its case.

Case No.	87 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	MILAN LABORATORIES (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00042233AM22
RA File Number	03AA04013716 AM22
Licence No and Date	0311003840/17/05/2021

Norms Committee Decision:

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	PHENOXYMETHYL PENICILLIN TABLETS BP 250 MG.(Each Tablets contains: Phenoxymethyl Penicillin Potassium equivalent to Phenoxymethyl Penicillin BP 250 mg) (Total Net Content = 6798.898 Kgs))	1 Number	1	Phenoxymethyl Potassium BP Penicillin	277.161 mg
2	PHENOXYMETHYL PENICILLIN TABLETS 500 MG((Each Tablet contains Phenoxymethyl Penicillin Potassium equivalent to Phenoxymethyl Penicillin BP 500mg) (Total Net Content = 7799.311 Kgs))	1 Number	2	Phenoxymethyl Potassium BP Penicillin	554.322 mg
3	PHENOXYMETHYL PENICILLIN ORAL SOLUTION(BP 125 MG/5ML (SYRUP).Each 5ml contains: Phenoxymethyl penicillin Potassium equivalent to Phenoxymethyl Penicillin BP 125mg) 100ML Bottle. (Total Net Content = 2633.020 Kgs))	1 Number	3	Phenoxymethyl Potassium BP Penicillin	2771.61 mg

4	PHENOXYMETHYL PENICILLIN ORAL SOLUTION(BP 250 MG/5ML (SYRUP).Each 5ml contains: Phenoxymethyl penicillin Potassium equivalent to Phenoxymethyl Penicillin BP 250mg) 100ML Bottle. (Total Net Content = 2771.610 Kgs))	1 Number	4	Phenoxymethyl Penicillin Potassium BP	5543.22 mg
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RA concerned may take further necessary action as per above decision of NC

Case No.	88 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00045345AM22
RA File Number	30AA04001247 AM22
Licence No and Date	3011000633/18/05/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to 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.	89 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00046861AM22
RA File Number	05AA04016543 AM22
Licence No and Date	0511002719/20/05/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Mar/202122/16 dated 08.04.2022 against advance authorization No. 0511006111 dt. 12.11.2021 , 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.
Meropenem with Sodium Carbonate USP (1 kg Meropenem Buffered)(Bulk Drug / Pharmacopeal Grade)	1	1	(4R,5S,6S)-3-[[[(3S,5S)-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6-[(1R)-1-hydroxyethyl]-4methyl-7-oxo-1-azabicyclo	0.8728 kg

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

Case No.	90 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	NASENSE LABS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00046900AM22
RA File Number	09AA04002898 AM22
Licence No and Date	0911000881/20/05/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Percentage yield of reaction at every step. ii. Copy of earlier norms approved.	

Case No.	91 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	TADIMETY AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00047898AM22
RA File Number	07AA04004515 AM22
Licence No and Date	0711001152/21/05/2021
Norms Committee Decision: The Committee considered the case as per agenda and 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 alongwith stage wise percentage yields on molar basis.
- iii. Complete technical details as per Annexure to Appendix 4E for chemical products.
- iv. Stoichiometric balance between import and export on molar basis.
- v. Details of indigenous input with quantity.

Case No.	92 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	TATVA CHINTAN PHARMA CHEM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00047933AM22
RA File Number	34AA04001536 AM22
Licence No and Date	3411000610/21/05/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **15/82-ALC4/2018 dated 22.03.2019** against advance authorization No. **3410044276 dt. 22.06.2018**, 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.
METHYL TRIBUTYL AMMONIUM CHLORIDE ASSAY 75 PERCENT (+/-2 PERCENT)	1 kg	1	TRIBUTYL AMINE ASSAY NLT 98.5 PERCENT	0.4642 kg

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

Case No.	93 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SAKAR HEALTHCARE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00099634AM22
RA File Number	08AA04004104 AM22
Licence No and Date	0811001574/25/05/2021

Norms Committee Decision:

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

- i. COA of import item from foreign supplier showing potency and wastage claimed on it.**

Case No.	94 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	DIAMINES AND CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00101253AM22
RA File Number	34AA04001451 AM22
Licence No and Date	3411000643/27/05/2021

Norms Committee Decision:

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

- i. COA of import item indicating percentage composition of various amines and other products.**
ii. Quantity and Commercial value of By-Product obtained.

Production / Consumption data for last three years duly certified by GST.

Case No.	95 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00102193AM22
RA File Number	08AA04005014 AM22
Licence No and Date	0811001601/28/05/2021

Norms Committee Decision:

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

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

v. Percentage composition of various Amines used in Export Product.

Case No.	96 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	UNITED MUD-CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00103082AM22
RA File Number	03AA04017853 AM22
Licence No and Date	0311004136/30/05/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Percentage net content of Dimer Acid in Export.	

Case No.	97 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	ATUL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00104366AM22
RA File Number	08AA04004876 AM22
Licence No and Date	0811001618/01/06/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: Stoichiometric balance to arrive at the quantity of Methanol asked on the basis of molecular weight, yield etc.	

Case No.	98 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00105763AM22
RA File Number	03AA04017165 AM22
Licence No and Date	0311004253/02/06/2021

Norms Committee Decision:

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

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

Case No.	99 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00107290AM22
RA File Number	34AA04002205 AM22
Licence No and Date	3411000694/04/06/2021

Norms Committee Decision:

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

- i. End use of export item.**
- ii. Commercial value of Low Boiler & High Boiler and Polymerised Material.**

Production / Consumption data for last three years duly certified by GST.

Case No.	100 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	TIDE INDUSTRIES
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00107366AM22
RA File Number	34AA04002212 AM22
Licence No and Date	3411000697/04/06/2021

Norms Committee Decision:

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

- i. End use of export item.**

ii. Commercial value of Low Boiler & High Boiler and Polymerised Material.

Production / Consumption data for last three years duly certified by GST

Case No.	101 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00107373AM22
RA File Number	03AA04018281 AM22
Licence No and Date	0311004321/04/06/2021

Norms Committee Decision:

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

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

Case No.	102 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	STERILE INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00108212AM22
RA File Number	05AA04019922 AM22
Licence No and Date	0511002989/05/06/2021

Norms Committee Decision:

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

- i. COA of Export item..**
- ii. COA of import item from foreign supplier..**
- iii. Copy of Master Batch Formula.**
- iv DML for export.**

Case No.	103 / NC/3/MEET/May/202223/4
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Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00109187AM22
RA File Number	03AA04022509 AM22
Licence No and Date	0311004402/07/06/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	104 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00109350AM22
RA File Number	03AA04023320 AM22
Licence No and Date	0311004415/08/06/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Density of each export item.	

Case No.	105 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	BEST VALUE CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00109428AM22
RA File Number	34AA04002141 AM22
Licence No and Date	3411000701/08/06/2021
Norms Committee Decision:	
Deferred for comments of TE	

Case No.	106 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	ALPHAMED FORMULATIONS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022

and Date	
HQ File Number	HQRNORM APPLY 00109478AM22
RA File Number	09AA04003622 AM22
Licence No and Date	0911001018/08/06/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	107 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00109532AM22
RA File Number	05AA04023341 AM22
Licence No and Date	0511003027/08/06/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Mar/202122/16 dated 08.04.2022** against advance authorization No. **0511006111 dt. 12.11.2021**, 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.
Meropenem with Sodium Carbonate USP (1 kg Meropenem Buffered)(Bulk Drug / Pharmacoepal Grade)	1	1	(4R,5S,6S)-3-[[[(3S,5S)-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6-[(1R)-1-hydroxyethyl]-4methyl-7-oxo-1-azabicyclo	0.8728 kg

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

Case No.	108 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	FRESENIUS KABI INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00109628AM22
RA File Number	03AA04019238 AM22

Licence No and Date	0311004420/08/06/2021
Norms Committee Decision:	
Deferred for comments of TE.	

Case No.	109 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SV PLASTOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00111363AM22
RA File Number	31AA04004163 AM22
Licence No and Date	3111000397/10/06/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm:	
i. Percentage purity of export product alongwith COA. Stoichiometric balance on molar basis and percentage yield to arrive at the quantity of raw material asked for.	

Case No.	110 / NC/3/MEET/May/202223/4	
Case Status	Case Approved	
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED	
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022	
HQ File Number	HQRNORM APPLY 00111397AM22	
RA File Number	03AA04009888 AM22	
Licence No and Date	0311004497/10/06/2021	
Norms Committee Decision:		
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3MEET/Jun/202122/2 dated 02.07.2021 against advance authorization No. 0311004496 dt. 10.06.2021 , 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:		
Sl. No.	Export Product	Qty.
1	GLIPIZIDE EXTENDED RELEASE TABLETS 10 MG. Each tablet contains (i) Glipizide USP- 10 mg(ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 29.70 mg (iii) Sentry Polyox WSR N80 FP NF- 178.10 mg (iv) Sentry Polyox WSR 303 NF- 100 mg. Net content (i) 459.46 Kgs (ii) 1364.59	1 Number

	Kgs (iii) 8182.96 Kgs (iv) 4594.59 Kgs.)	
2	GLIPIZIDE EXTENDED RELEASE TABLETS 5 MG. Each tablet contains (i) Glipizide USP- 5 mg((ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 20.40 mg (iii) Sentry Polyox WSR N80 FP NF- 89.05 mg (iv) Sentry Polyox WSR 303 NF- 50 mg. Net content (i) 182.43 Kgs (ii) 744.32 Kgs (iii) 3249.12 Kgs (iv) 1824.33 Kgs.)	1 Number
3	GLIPIZIDE EXTENDED RELEASE TABLETS 2.5 MG. Each tablet contains (i) Glipizide USP- 2.5 mg((ii) Eastman (TM Cellulose Acetate (CA 398-10NF/EP)- 20.40 mg (iii) Sentry Polyox WSR N80 FP NF- 89.05 mg (iv) Sentry Polyox WSR 303 NF- 50 mg. Net content (i) 33.78 Kgs (ii) 275.68 Kgs (iii) 1203.38 Kgs (iv) 675.68 Kgs.)	1 Number

Sl. No.	Import Items	For export of 1 Number of Tablet		
		2.5 mg	5.0 mg	10.0 mg
1	GLIPIZIDE USP	2.55 mg	5.10 mg	10.20 mg
2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	20.40 mg	20.40 mg	29.70 mg
3	SENTRY POLYOX WSR N80 FP NF	89.05 mg	89.05 mg	178.10 mg
4	SENTRY POLYOX WSR 303 NF	50.00 mg	50.00 mg	100.00 mg

RA may take appropriate action as per the decision of Norms Committee.

Case No.	111 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	YASHO INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00112010AM22
RA File Number	03AA04024304 AM22
Licence No and Date	0311004509/10/06/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. NC/3/MEET/Apr/202223/1 dated 29.04.2022 against advance authorization No. 0311005604 dt. 29.04.2022 , 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.
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.	112 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	TINA ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00112444AM22
RA File Number	05AA04025398 AM22
Licence No and Date	0511003109/11/06/2021

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from earlier decision for same export product in Meeting No. **NC/3/MEET/Jan/202122/13 dated 21.01.2022** against advance authorization No. **0510413266 dt. 09.01.2020**, 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.
ISOPROPYLATED PHENYL PHOSPHATE (LIQUID STANDARD)	1 kg	1	ORTHO ISOPROPYL PHENOL	0.950 kg
		2	PHOSPHOROUS	0.079 kg

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

Case No.	113 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	COMBITIC GLOBAL CAPLET PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00112558AM22
RA File Number	33AA04001775 AM22
Licence No and Date	3311000287/11/06/2021

Norms Committee Decision:

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	Azithromycin Tablet IP/BP/USP 250mg.((Each film coated Tablet Contains 267.75mg. Azithromycin Dihydrate IP/BP/USP Equivalent to 250mg. Azithromycin))	1 Number	1	Azithromycin Dihydrate IP	267.24 mg/Tablet
2	Azithromycin Tablets IP/BP/USP 500mg.((Each film coated Tablet Contains 535.50mg. Azithromycin Dihydrate IP/BP/USP Equivalent to 500mg. Azithromycin))	1 Number	2	Azithromycin Dihydrate IP	534.48 mg/Tablet
3	Cefixime and Azithromycin Tablets((Each Film Coated Tablet Contains Cefixime Trihydrate IP 228.48mg. Equivalent to Cefixime 200mg. Azithromycin Dihydrate IP 267.75mg. Equivalent to Azithromycin 250mg.))	1 Number	3	Azithromycin Dihydrate IP	267.24 mg/Tablet
			6	Cefixime Trihydrate IP	228.294 mg/Tablet
4	Cefixime Tablets IP/BP/USP 200mg.((Each Film Coated Tablet Contains Cefixime Trihydrate IP/BP/USP 228.48mg. Equivalent to Cefixime 200mg.))	1 Number	4	Cefixime Trihydrate IP	228.294 mg/Tablet
5	Cefixime Tablets IP/BP/USP 400mg.((Each Film Coated Tablet Contains Cefixime Trihydrate IP/BP/USP 456.96mg. Equivalent to Cefixime 400mg.))	1 Number	5	Cefixime Trihydrate IP	456.588 mg/Tablet

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

Case No.	114 / NC/3/MEET/May/202223/4
Case Status	Case Rejected
Party Name	SAURAV CHEMICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00113426AM22
RA File Number	30AA04004647 AM22
Licence No and Date	3011000736/12/06/2021
Norms Committee Decision: The Committee considered the case as per agenda and reply of firm and it was observed that the firm has not given any technical details in its reply. In view of above, the Committee decided to reject the case.	

Case No.	115 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00113434AM22
RA File Number	03AA04015087 AM22
Licence No and Date	0311004561/12/06/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: i. Description of all Excipients shown in items to be imported may be furnished as per their chemical name. ii. Details of Packaging Material may be furnished. iii. Copy of Master Batch Formula for all export items indicating net content of inputs in each export.	

Case No.	116 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	SV PLASTOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00113697AM22

RA File Number	31AA04007148 AM21
Licence No and Date	3111000400/14/06/2021
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to call for following information / documents from the firm: - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights alongwith 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. - Production / Consumption data duly certified by GST for the year 2018-19, 2019-20 and 2020-21. - Percentage purity of export product alongwith its COA.	

Case No.	117 / NC/3/MEET/May/202223/4
Case Status	Case Approved
Party Name	MILAN LABORATORIES (INDIA) PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM APPLY 00163823AM22
RA File Number	03AA04064805 AM22
Licence No and Date	0311006209/16/08/2021

Norms Committee Decision:

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

Sl. No.	Export product	Qty.	Sl. No.	Import items	Qty.
1	ERYTHROMYCIN TABLETS 250 MG((Each Tablets contains: ERYTHROMYCIN STEARATE 413.25 mg equivalent to ERYTHROMYCIN BP /PH Eur 250 mg) (Net content / Tablet- 413.250 mg.Total Net wt = 4580.050 Kgs	11083000 Number	1	ERYTHROMYCIN STEARATE EP / CEP	4580.05 kg
2	ERYTHROMYCIN TABLETS 500 MG((Each Tablets contains: ERYTHROMYCIN STEARATE 826.50 mg equivalent to ERYTHROMYCIN BP /PH Eur 500 mg) (Net content / Tablet-	1755000 Number	2	ERYTHROMYCIN STEARATE EP / CEP	1450.5 kg

	826.500 mg.Total Net wt = 1450.508 Kgs)				
RA concerned may take further necessary action as per above decision of NC.					

Case No.	118 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00397092AM22
RA File Number	08AA04023464 AM22
Licence No and Date	0811002450/31/08/2021
Norms Committee Decision:	
The Committee considered the request of firm for enhancement of norms and it was decided to call firm for attending <u>Personal Hearing</u> before Norms Committee alongwith relevant documents to explain its case	

Case No.	119 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00397104AM22
RA File Number	08AA04025507 AM22
Licence No and Date	0811002517/06/09/2021
Norms Committee Decision:	
The Committee considered the request of firm for enhancement of norms and it was decided to call firm for attending <u>Personal Hearing</u> before Norms Committee alongwith relevant documents to explain its case	

Case No.	120 / NC/3/MEET/May/202223/4
Case Status	Case Deferred
Party Name	INTAS PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202223/ 4 and 17/06/2022
HQ File Number	HQRNORM REVIW00397111AM22
RA File Number	08AA04030678 AM22
Licence No and Date	0811002770/04/10/2021
Norms Committee Decision:	

The Committee considered the request of firm for enhancement of norms and it was decided to call firm for attending **Personal Hearing** before Norms Committee alongwith relevant documents to explain its case