



सत्यमेव जयते

Government of India / भारत सरकार

Ministry of Commerce and Industry / वाणिज्य और उद्योग मंत्रालय

Department of Commerce / वाणिज्य विभाग

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

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

रोड, नई दिल्ली

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(DES - III SECTION)

MINUTES OF THE NORMS COMMITTEE- III**MEETING No.** NC/3/MEET/May/202425/4**DATED:** 06/06/2024Please 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.
- IV. RAs shall ensure compliance of SION, General Notes and Chapter Notes wherever applicable.
- V. RAs shall also ensure that authorization is issued or redeemed based on the wastages/consumption as ratified by the Committee or as per wastages claimed in the application, whichever is less. In this regard, full compliance of the provisions of Para 4.12 of FTP, Para 4.16, Para 4.21 and Para 4.51 of HBP shall be made.

Meeting No. NC/3/MEET/May/202425/4 dated 06/06/2024 of Norms Committee - III for the year 2024-25 was held on 06/06/2024 under the Chairmanship of Shri Rakesh Kumar, 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-2023.

The following members were present in the meeting:-

S.No.	Name and Designation of Representatives	Department
1	Shri Rakesh Kumar, Addl. DGFT	DGFT(HQ)

2	Shri Raman Kumar, Deputy DGFT	DGFT(HQ)
3	Shri Dinesh Narain Mathur, Technical Expert	Consultant (Pharma)
4	Shri Shaish Kumar, Technical Expert	Consultant (Chemical)
5	Shri Nand Lal, Technical Expert	Consultant (Chemical)
6	Shri Uttam Dey Sarkar, ASO	DGFT (HQ)

Case Details and Decision(s):

Case No.	1 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	AMOLI ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009045AM24
RA File Number	039404000337 AM12
Licence No and Date	0310646104/03/08/2011
Norms Committee Decision: The committee considered the request of firm for review of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Particle size of import item is not mentioned in Certificate of Analysis (CoA) to show any manufacturing activity (Micronization) in the process. 2. Above details alongwith Bill of Entry of import may be furnished in support of its claim.	

Case No.	2 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009259AM24
RA File Number	039504000262 AM13
Licence No and Date	0310705888/22/08/2012
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	3 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	ADCOCK INGRAM LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009069AM24
RA File Number	072404000207 AM15
Licence No and Date	0710106682/16/09/2014

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ADCO DOL TABS - Paracetamol 450mg + Codeine Phosphate 10mg+ Caffeine 45mg + Doxylamine Succinate 5mgTablets ((No.ofTablets-99033310) (Para-44564.990+Codeine-990.333+Caff-4456.499+Doxy-495.167Kgs+ColQuiYelLake-451.592+ Col Qui Yel WS - 240.651 KGS))	1 Million Tablets	1	DOXYLAMINE SUCCINATE USP /Ph. Eur Grade	5.10 kg.
		2	COLOUR QUINOLINE YELLOW WS (SPECTRACOL)	10.2 kg.
		3	COLOUR QUINOLINE YELLOW LAKE IH (SPECTRACOL)	2.43 kg.
		4	CODEiNE PHOSPHATE BP / EP / USP / PH.EUR	4.56 kg.
		5	PARACETAMOL GRANULES DC 83S (KRISOPAP - 83S)	454.5 kg.

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

Case No.	4 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009043AM24
RA File Number	522404000058 AM15
Licence No and Date	5210041428/13/02/2015
Norms Committee Decision:	

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting **No. NC/3/MEET/Sep/202324/13 dated 14/09/2023** against advance authorization **No.5211000803** dated **01/06/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1,(3 CL PHENYL)-4-(3-CL PHENYL) PIPERAZINE HCL - 99% MIN.	1 kg.	1	1,3-BROMO CHLORO PROPANE - 99.5% MIN.	1.045 kg.

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

Case No.	5 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	HERBOCHEM
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009084AM24
RA File Number	092404000148 AM16
Licence No and Date	0910062238/23/06/2015

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Extract Ipecacuanha (Ipecac Conc.8% alkaloid)	1 kg.	1	Ipecacuanha (Ipecac) Roots (Dry Roots) containing minimum 2 % Alkaloids	4.00 kg.

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

Case No.	6 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	SHREE BANKEY BEHARI LAL AROMATICS
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008908AM24
RA File Number	NA
Licence No and Date	0510402031/21/03/2017

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.10/82-ALC4/2019 dated 29/11/2019** against advance authorization **No.0510403552 dated 01/08/2019**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CARVACROL	1 kg.	1	D-LIMONENE (LIMONENE CITRUS TERPENE, ORANGE TERPENE, BRAZILIAN CITRUS TERPENE, STANDARD CITRUS TERPENE, ORANGE OIL)	1.48 kg.

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

Case No.	7 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024

and Date														
HQ File Number	HQRNORM REVIW00009048AM24													
RA File Number	522404000068 AM19													
Licence No and Date	5210042870/18/12/2018													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting No. NC/3/MEET/Oct/202324/15 dated 13/10/2023 against advance authorization No.5210042870 dated 18/12/2018 ; it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">4-HYDROXY COUMARIN (by Acetyl Salicylic Acid route)</td><td rowspan="2">1 kg.</td><td>1</td><td>Acetyl Salicylic Acid (For Industrial Use)</td><td>1.56 kg.</td></tr><tr><td>2</td><td>Ethyl Aceto Acetate</td><td>1.147 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	4-HYDROXY COUMARIN (by Acetyl Salicylic Acid route)	1 kg.	1	Acetyl Salicylic Acid (For Industrial Use)	1.56 kg.	2	Ethyl Aceto Acetate	1.147 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
4-HYDROXY COUMARIN (by Acetyl Salicylic Acid route)	1 kg.	1	Acetyl Salicylic Acid (For Industrial Use)	1.56 kg.										
		2	Ethyl Aceto Acetate	1.147 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	8 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	VDH ORGANICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00008896AM24
RA File Number	052404000721 AM19
Licence No and Date	0510410010/20/03/2019
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Percentage wise yield not given.	

Case No.	9 / NC/3/MEET/May/202425/4
Case Status	Case Rejected
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009294AM24
RA File Number	082404000026 AM20
Licence No and Date	0810145127/30/04/2019
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	10 / NC/3/MEET/May/202425/4
Case Status	Case Rejected
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009291AM24
RA File Number	082404000005 AM20
Licence No and Date	0810145144/01/05/2019
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	11 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	RAVESHIA ORGANICS LLP
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009054AM24

RA File Number	039504000204 AM20
Licence No and Date	0310829355/30/05/2019
Norms Committee Decision: The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- Complete technical details as per Annexure to Appendix 4E for chemical products.	

Case No.	12 / NC/3/MEET/May/202425/4																			
Case Status	Case Approved																			
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED																			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024																			
HQ File Number	HQRNORM REVIW00000046AM25																			
RA File Number	318304000051 AM20																			
Licence No and Date	3110067490/02/08/2019																			
Norms Committee Decision:																				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import items in meeting No. NC/3/MEET/Dec/202324/19 dated 05/01/2024 against advance authorization No.3111001358 dated 17/05/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																				
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="4">DNOVO BP818 (Tetra Methyl Bisphenol F)</td><td rowspan="4">1 kg.</td><td>1</td><td>OCP 50</td><td>1.100 kg.</td></tr><tr><td>2</td><td>Methanol</td><td>0.66 kg.</td></tr><tr><td>3</td><td>Catalyst (Katalco 715)</td><td>0.004 kg.</td></tr><tr><td>4</td><td>Paraformaldehyde</td><td>0.141 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	DNOVO BP818 (Tetra Methyl Bisphenol F)	1 kg.	1	OCP 50	1.100 kg.	2	Methanol	0.66 kg.	3	Catalyst (Katalco 715)	0.004 kg.	4	Paraformaldehyde	0.141 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.																
DNOVO BP818 (Tetra Methyl Bisphenol F)	1 kg.	1	OCP 50	1.100 kg.																
		2	Methanol	0.66 kg.																
		3	Catalyst (Katalco 715)	0.004 kg.																
		4	Paraformaldehyde	0.141 kg.																

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

Case No.	13 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	DEEPAK NOVOCHEM TECHNOLOGIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00000048AM25
RA File Number	318304000087 AM20
Licence No and Date	3110067548/30/09/2019
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. The stage wise percentage yield of the reaction and to calculate the requirement of OCP on the basis of constituent ratio. 2. Justification of yield of the reaction with calculation of requirement of all the raw materials with Annexure to Appendix-4E	

Case No.	14 / NC/3/MEET/May/202425/4			
Case Status	Case Approved			
Party Name	REFLUX PHARMACEUTICALS			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024			
HQ File Number	HQRNORM REVIW00008045AM24			
RA File Number	039504000931 AM20			
Licence No and Date	0310833815/01/01/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to review ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				

TOLFENAMIC ACID (BULK DRUG)	1 kg.	1	ORTHO CHLOROBENZOIC ACID	1.255 kg.
		2	3-CHLORO-2-METHYLANILINE	0.750 kg.

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

Case No.	15 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009300AM24
RA File Number	052404000670 AM20
Licence No and Date	0510413367/17/01/2020
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity.	

Case No.	16 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009301AM24
RA File Number	052404000729 AM20
Licence No and	0510413656/19/02/2020

Date	
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity.	

Case No.	17 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	SUPERMINT EXPORTS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009299AM24
RA File Number	052404000071 AM21
Licence No and Date	0510414288/29/05/2020
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity.	

Case No.	18 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	KOSHA CHEMTECH PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024

and Date	
HQ File Number	HQRNORM REVIW00000014AM25
RA File Number	039404000306 AM21
Licence No and Date	0310837580/10/08/2020
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity.	

Case No.	19 / NC/3/MEET/May/202425/4			
Case Status	Case Approved			
Party Name	CONCORD BIOTECH LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024			
HQ File Number	HQRNORM APPLY 00009181AM24			
RA File Number	NA			
Licence No and Date	0810149102/23/11/2020			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import itemt in meeting No. NC/3/MEET/Apr/20232419 dated 28/04/2023 against advance authorization No. 0810145581 dated 27/06/2019 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty	Sl. No.	Import Item	Qty Allowed
EVEROLIMUS PREMIX 9.09 (PERCENTAGE) (POWDER FOAM)	20.65 kg	1	(3S 6R 7E 9R 10R 14S 15E 17E 19E 21S 23S 26R 27R 34 AS) 9 10 12 13 14 21 22 23 24 25 26 27 32 33 34 34A-HEXADECAHYDRO – 9 27 – DIHYROXY - 3- ((1R) – 2 - ((1S,3R,4R) - 4- HYDROXY – 3 - METHOXYCYCLOHEXYL) - 1 METHYLETHYL) - 10 21 – DIMETHOXY – 6 8 12 14 20 26 –	25.0 Kg

			HEXAMETHYL – 23 27 – EPOXY - 3H – PYRIDO (2 1C) (1 4) OXAAZA CYCLOHENTRIACONTINE 1 5 11 28 29 (4H 6H 31H) - PENTONE (SIROLIMUS CRUDE)	
RA concerned may take further necessary action as per above decision of NC.				

Case No.	20 / NC/3/MEET/May/202425/4
Case Status	Case Rejected
Party Name	ORGANIC INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00000057AM25
RA File Number	06AA04002281 AM21
Licence No and Date	0611000019/16/12/2020
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm has surrendered the license to RA, Kanpur. The Committee, therefore, decided to reject the case.	

Case No.	21 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	REFLUX PHARMACEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00007988AM24
RA File Number	NA
Licence No and Date	0311001445/03/02/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TOLFENAMIC ACID	1 kg.	1	3 CHLORO 2 METHYLANILINE 99 PERCENT MIN	0.750 kg.
		2	ORTHO CHLORO BENZOIC ACID 99 PERCENT MIN	1.255 kg.
		3	DIMETHYL FORMAMIDE 99 POINT 9 PERCENT	4.77 kg.

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

Case No.	22 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	MAHIMA LIFESCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00000099AM25
RA File Number	05AA04029372 AM21
Licence No and Date	0511001191/09/02/2021
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. The Assay of import and export item is not matching. 2. Particlesize of import item is not given. 3. Copy of Bill of Entry for import item.	

Case No.	23 / NC/3/MEET/May/202425/4
Case Status	Case Approved

Party Name	INDOCO REMEDIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00004407AM24
RA File Number	03AA04023340 AM21
Licence No and Date	0311001698/16/02/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Brimonidine Tartrate and Timolol 2mg/ml 5mg/ml Eye Drops solution (5 ml Bottle) (Each ml Contains : BrimonidineTartrate 2 mg and Timolol Maleate equivalent toTimolol 5 mg) (Each 5 ml Contains: Brimonidine Tartrate10 mg and Timolol Maleate25mg)	1 Number	1	Brimonidine	Not imported
		2	Bottle	Relevant as per Packing Policy & General Notes.
		3	Cap	Relevant as per Packing Policy & General Notes.
		4	Dropper	Relevant as per Packing Policy & General Notes.
		8	Bottle	Relevant as per Packing Policy & General Notes.
		9	Cap	Relevant as per Packing Policy & General Notes.
		10	Dropper	Relevant as per Packing Policy & General Notes.
		14	Timolol Maleate	25.50 mg / bottle
		15	Bottle	Relevant as per Packing Policy & General Notes.

		16	Cap	Relevant as per Packing Policy & General Notes.
		17	Dropper	Relevant as per Packing Policy & General Notes.
Brimonidine Tartrate and Timolol 2mg/ml 5mg/ml Eye Drops solution (10 ml Bottle) ((Each ml Contains : Brimonidine Tartrate 2 mg and Timolol Maleate equivalent to Timolol 5mg) (Each 10ml Contains: Brimonidine Tartrate 20mg and Timolol Maleate 50mg)	1 Number	5	Bottle	Relevant as per Packing Policy & General Notes.
		6	Cap	Relevant as per Packing Policy & General Notes.
		7	Dropper	Relevant as per Packing Policy & General Notes.
		11	Bottle	Relevant as per Packing Policy & General Notes.
		12	Cap	Relevant as per Packing Policy & General Notes.
		13	Dropper	Relevant as per Packing Policy & General Notes.
		18	Brimonidine	Not imported
		19	Timolol Maleate	51.00 mg / bottle
		20	Bottle	Relevant as per Packing Policy & General Notes.
		21	Cap	Relevant as per Packing Policy & General Notes.
		22	Dropper	Relevant as per Packing Policy & General Notes.

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

Case No.	24 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	AETHER INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00000359AM25
RA File Number	52AA04007931 AM21
Licence No and Date	5211000485/16/03/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ORGANIC CHEMICAL- ORGANIC-PHENOLS, PHENOL ALCOHOLS AND THEIR DERIVATIVES PHENOLALCOHOLS, THEREOF: 4-(2-METHOXYETHYL) PHENOL	1 kg.	1	PARA CHLORO PHENOL	2.42 kg.
		2	TETRAHYDROFURAN	1.00 kg.
		3	MAGNESIUM METAL TURNING	0.37 kg.

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

Case No.	25 / NC/3/MEET/May/202425/4
Case Status	Case Rejected
Party Name	ASCENT FINECHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024

HQ File Number	HQRNORM REVIW00009292AM24
RA File Number	08AA04009431 AM22
Licence No and Date	0811001850/25/06/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and it was observed that the firm has surrendered the license to RA, Kanpur. The Committee, therefore, decided to close the case.	

Case No.	26 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	SUNDYOTA NUMANDIS PROBIOCEUTICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00000168AM25
RA File Number	08AA04021121 AM22
Licence No and Date	0811002324/16/08/2021

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PROTEFLOR IBS SACHET (BIFIDOBACTERIUM LONGUM W11 + Fructo oligosaccharide)	3750 kg.	1	BIFIDOBACTERIUM LONGUM W11 ID 1114	76.5 kg.
		2	FRUCTO OLIGOSACCHARIDE	1912.5 kg.
		3	ISOMALT 44.16 PERCENTAGE	1689.12 kg.
		4	ORANGE CITRUS POWDER FLAVOUR 70477	57.375 kg.
		5	COLLOIDAL SILICON DIOXIDE	38.25 kg.
		6	MAGNESIUM SULPHATE ANHYDROUS	38.25 kg.

		7	STEVIOL GLYCOSIDE	13.005 kg.
Note: RA will check the number of Sachet to overall weight of export product. RA concerned may take further necessary action as per above decision of NC.				

Case No.	27 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	SUMAR BIOTECH LLP
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00000315AM25
RA File Number	08AX04000034 AM22
Licence No and Date	0811003488/20/12/2021
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	28 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009044AM24
RA File Number	52AX04000016 AM22
Licence No and Date	5211001759/23/12/2021
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import itemt in meeting No. NC/3/MEET/Sep/202324/13 dated 14/09/2023 against advance authorization No.5211000803 dated 01/06/2021, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
1-(3-CHLORO PHENYL)4-(3-CHLORO PROPYL) PIPERAZINE HCL	1 kg.	1	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.	29 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	GUPTA AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009287AM24
RA File Number	05AX04001230 AM22
Licence No and Date	0511010862/10/03/2022

Norms Committee Decision:

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

- 1. The chemical reaction indicating molecular weight of both reactants and products with yield and calculation.**

Case No.	30 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	GUPTA AROMATICS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009288AM24
RA File Number	05AX04001267 AM22

Licence No and Date	0511010970/14/03/2022
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. The chemical reaction indicating molecular weight of both reactants and products with yield and calculation.	

Case No.	31 / NC/3/MEET/May/202425/4
Case Status	Case Rejected
Party Name	AMI ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009049AM24
RA File Number	52AX04000101 AM22
Licence No and Date	5211002273/30/03/2022
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	32 / NC/3/MEET/May/202425/4
Case Status	Case Rejected
Party Name	ORGANIC INDIA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00000058AM25
RA File Number	06AX04000155 AM22
Licence No and Date	0611001257/31/03/2022
Norms Committee Decision: The Committee considered the case as per agenda and it was observed that the firm vide e-mail dated 09/08/2023 has informed that they had paid customs duty and will surrender the licence. The Committee,	

therefore, decided to **withdraw** the application of the firm.

Case No.	33 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00000422AM25
RA File Number	30AX04000065 AM23
Licence No and Date	3011002150/23/05/2022

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Injection Urokinase (Each vial contains 500000 IU of Urokinase)	1000 Vials	1	Urokinase (purified)	1043.46 mg.
		2	Mannitol 0.5%	128.52 gm.
		3	Sodium Chloride (50 mg/vial)	128.52 mg.
		4	Sodium Hydroxide	3.06 gm

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

Case No.	34 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	USV PRIVATE LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024													
HQ File Number	HQRNORM APPLY 00002501AM23													
RA File Number	03AX04002642 AM23													
Licence No and Date	0311016913/05/08/2022													
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1" data-bbox="197 675 1430 1022"> <thead> <tr> <th>Export Product</th> <th>Qty.</th> <th>Sl. No.</th> <th>Import Items</th> <th>Qty. allowed.</th> </tr> </thead> <tbody> <tr> <td>Doxycycline Hyclate DR Tablets USP 200 mg , 60'S US((2,333 Bottles X 60 Per Bottles = 1,39,980 Tablets)</td> <td>1 Number</td> <td>1</td> <td>Doxycyclin e Hyclate USP</td> <td>230.80 mg</td> </tr> </tbody> </table> RA concerned may take further necessary action as per above decision of NC.					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Doxycycline Hyclate DR Tablets USP 200 mg , 60'S US((2,333 Bottles X 60 Per Bottles = 1,39,980 Tablets)	1 Number	1	Doxycyclin e Hyclate USP	230.80 mg
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Doxycycline Hyclate DR Tablets USP 200 mg , 60'S US((2,333 Bottles X 60 Per Bottles = 1,39,980 Tablets)	1 Number	1	Doxycyclin e Hyclate USP	230.80 mg										

Case No.	35 / NC/3/MEET/May/202425/4
Case Status	Case Rejected
Party Name	SRF LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00003064AM23
RA File Number	05AX04001671 AM23
Licence No and Date	0511014757/12/09/2022
Norms Committee Decision: The firm vide e-mail dated 08/05/2024 has informed that they have surrendered their above license. In view of e-mail of firm, the Committee decided to withdraw the application of the firm.	

Case No.	36 / NC/3/MEET/May/202425/4				
Case Status	Case Approved				
Party Name	SHREE MAHADEV INTERMEDIATE				
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024				
HQ File Number	HQRNORM REVIW00005358AM24				
RA File Number	34AX04000640 AM23				
Licence No and Date	3411002862/04/10/2022				
Norms Committee Decision:					
The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					

Case No.	37 / NC/3/MEET/May/202425/4			
Case Status	Case Approved			
Party Name	BALAJI SPECIALITY CHEMICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024			
HQ File Number	HQRNORM REVIW00009183AM24			
RA File Number	31AX04000194 AM23			
Licence No and Date	3111001751/18/10/2022			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/25 dated 11/03/2024 against advance authorization No. 3111000876 dated 14/01/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
</				

		No.		
ETHYLENEDIAMINE	1 kg.	1	MONO ETHANOL AMINE	1.06 kg.
		2	AMMONIA ANHYDROUS	0.294 kg.
DI ETHYLENE TRI AMINE	1 kg.	3	MONO ETHANOL AMINE	1.184 kg.
		4	AMMONIA ANHYDROUS	0.165 kg.
AMINO ETHYL ETHANOL AMINE	1 kg.	5	MONO ETHANOL AMINE	1.173 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	38 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	PANACEA BIOTEC LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00000471AM25
RA File Number	05AX04002301 AM23
Licence No and Date	0511015737/10/11/2022
Norms Committee Decision:	
The Committee considered the request of firm for fixation of ad-hoc norms and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

(Each vial of 5.0ml contains 10 dose) with Vaccine Vial Monitor		3	Pertussis Bulk	86.46 Litre
		4	Aluminium Phosphate Gel	6.875 kg.
		5	Electronic Temperature Data Logger	126.25 Numbers
		6	Rubber Stopper	1015000 Numbers
		7	VVM Dot 14	1015000 Numbers
		8	Ags Hb Purification Mabs Column	5.4 Litre
		9	Tetanus Toxoid for Conjugation	6.15 Litre
RA concerned may take further necessary action as per above decision of NC.				

Case No.	39 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	CANPEX CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009170AM24
RA File Number	31AX04000319 AM23
Licence No and Date	3111001972/19/01/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Feb/202324/23 dated 19/02/2024 against advance authorization No. 3111001583 dated 22/07/2022, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CYANAMIDE 50% SOLUTION	1 kg.	1	CALCIUM CYANAMIDE (Purity 63% as per CoA)	1.913 kg.

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

Case No.	40 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	SYNERGIA SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00006312AM23
RA File Number	03AX04005369 AM23
Licence No and Date	0311021429/14/02/2023

Norms Committee Decision:

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

- 1. Specific quantity of raw material used alongwith copy of Bill of Entry.**
- 2. Copy of Shipping Bills of export product.**

Case No.	41 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	HETERO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001083AM24
RA File Number	09AX04000105 AM24
Licence No and	0911005109/24/05/2023

Date				
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
(3R)-TETRAHYDRO-3-FURANYL-4-METHYLBENZENE SULFONATE (Diloxanide furoate, Cimetidine, Oxytclozanide, Famotidine:)	1 kg.	1	Tetra Hydro Furan	4.00 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	42 / NC/3/MEET/May/202425/4			
Case Status	Case Approved			
Party Name	INTAS PHARMACEUTICALS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024			
HQ File Number	HQRNORM APPLY 00001120AM24			
RA File Number	08AX04000305 AM24			
Licence No and Date	0811008290/25/05/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
CAPTOPRIL TABLETS 12.5 MG (EACH UNCOATED TABLET CONTAINS: CAPTOPRIL PH. EUR. 12.5 MG)	1 Number	1	CAPTOPRIL EP / BP / IP / USP / PH. EUR.	12.75 mg.

CAPTOPRIL TABLETS 25 MG (EACH UNCOATED TABLET CONTAINS: CAPTOPRIL PH. EUR. 25 MG)	1 Number	2	CAPTOPRIL EP / BP / IP / USP / PH. EUR.	25.50 mg.
CAPTOPRIL TABLETS 50 MG (EACH UNCOATED TABLET CONTAINS: CAPTOPRIL PH. EUR. 50 MG [IN WHICH ACTIVE INGREDIENT CAPTOPRIL USED IS 48.375 KGS])	1 Number	3	CAPTOPRIL EP / BP / IP / USP / PH. EUR.	51.00 mg

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

Case No.	43 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	AGRO SOLVENT PRODUCTS PVT LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001107AM24
RA File Number	56AX04000449 AM23
Licence No and Date	5611001909/25/05/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	44 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	PAYAL POLYPLAST PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001099AM24
RA File Number	05AX04000523 AM24

Licence No and Date	0511018990/25/05/2023			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jun/202324/8 dated 24/04/2023 against advance authorization No. 0511018482 dated 24/04/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Di Iso Butyl Phthalate (DIBP) (Oily Liquid Phthalate Easter)	1 kg.	1	Phthalic Anhydride	0.560 kg.
		2	Iso Butanol	0.560 kg.

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

Case No.	45 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001097AM24
RA File Number	03AX04000687 AM24
Licence No and Date	0311023887/25/05/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Justification for low yield of 61%. 2. Production/Consumption data certified by Auditor of the firm.	

Case No.	46 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	OC SPECIALITIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001095AM24
RA File Number	03AX04000858 AM24
Licence No and Date	0311023883/25/05/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Nov/202324/16** dated **17/11/2023** against advance authorization **No.0311015227** dated **03/06/2022**; it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
2,3 DI CHLORO PYRIDINE	1 kg.	1	3 AMINO PYRIDINE	1.0 kg.
		2	HYDROGEN PEROXIDE 50 %	0.637 kg.
		3	SODIUM NITRITE	0.687 kg.
		4	CAUSTIC SODA LYE (SODIUM HYDROXIDE LYE)	6.33 kg.

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

Case No.	47 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	VERGO PHARMA RESEARCH LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001091AM24
RA File Number	03AX04000834 AM24
Licence No and Date	0311023871/25/05/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
AMANTADINE HYDROCHLORIDE 100 MG	1 Number Capsule	1	AMANTADINE HYDROCHLORIDE	102 mg.

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

Case No.	48 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	ASG BIOCHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001122AM24
RA File Number	05AX04001792 AM23
Licence No and Date	0511019003/26/05/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/June/202122/2 dated 02/07/2021** against advance authorization **No.0511002814** dated **26/05/2021**; it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Allylestrenol (Steroidal hormones)	1 kg.	1	Norandrostenedione	1.45 kg

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

Case No.	49 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001153AM24
RA File Number	03AX04000851 AM24
Licence No and Date	0311023981/26/05/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No. NC/3/MEET/Sep/202324/14** dated **27/09/2023** against advance authorization **No. 0311026363 dated 16/08/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
LUMEFANTRINE	1 kg.	1	9H FLUORENE	0.90 kg.
		2	Di N Butylamine	0.50 kg.
		3	Sodium Borohydride	0.060 kg.
		4	Para Chloro Benzaldehyde	0.3476 kg.
		5	Di Methyl Formamide	0.555 kg.

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

Case No.	50 / NC/3/MEET/May/202425/4
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Case Status	Case Deferred
Party Name	VASISTA PHARMA CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001152AM24
RA File Number	26AX04000028 AM24
Licence No and Date	2611000961/26/05/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	51 / NC/3/MEET/May/202425/4															
Case Status	Case Approved															
Party Name	MANKIND PHARMA LIMITED															
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024															
HQ File Number	HQRNORM APPLY 00001166AM24															
RA File Number	05AX04000563 AM24															
Licence No and Date	0511019054/29/05/2023															
Norms Committee Decision:																
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Cynacobalamin Injection USP, 1000mcg/ml,</td><td>3625000 Numbers</td><td>1</td><td>CYANOCOBALAMIN USP</td><td>3987.5 gm.</td></tr><tr><td>Cynacobalamin Injection USP, 10000mcg/10ml (1000mcg/ml),</td><td>56250 Numbers</td><td>2</td><td>CYANOCOBALAMIN USP</td><td>608.75 gm</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Cynacobalamin Injection USP, 1000mcg/ml,	3625000 Numbers	1	CYANOCOBALAMIN USP	3987.5 gm.	Cynacobalamin Injection USP, 10000mcg/10ml (1000mcg/ml),	56250 Numbers	2	CYANOCOBALAMIN USP	608.75 gm
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.												
Cynacobalamin Injection USP, 1000mcg/ml,	3625000 Numbers	1	CYANOCOBALAMIN USP	3987.5 gm.												
Cynacobalamin Injection USP, 10000mcg/10ml (1000mcg/ml),	56250 Numbers	2	CYANOCOBALAMIN USP	608.75 gm												
RA concerned may take further necessary action as per above decision of NC.																

Case No.	52 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	AARTI PHARMALABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001158AM24
RA File Number	03AX04000849 AM24
Licence No and Date	0311024010/29/05/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	53 / NC/3/MEET/May/202425/4													
Case Status	Case Approved													
Party Name	ADCOCK INGRAM LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024													
HQ File Number	HQRNORM APPLY 00001161AM24													
RA File Number	07AX04000277 AM24													
Licence No and Date	0711007675/29/05/2023													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jan/202324/20 dated 18/01/2024 against advance authorization No. 0711004714 dated 20/07/2022 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td rowspan="2">FERROUS FORTE TABLETS((Vitamin C (as Ascorbic Acid) -71mg (248.500 KGS) +Iron (From Ferrous Bisglycinate Chelate- 126mg (441.000 KGS) With Other Essential Vitamins & Minerals (No of Tabs-3500000))</td><td rowspan="2">1 Number</td><td>1</td><td>ASCORBIC ACID DC 97 Percentage -SF. I.H</td><td>63.087 mg.</td></tr><tr><td>2</td><td>IRON BISGLYCINATE</td><td>122.400 mg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	FERROUS FORTE TABLETS((Vitamin C (as Ascorbic Acid) -71mg (248.500 KGS) +Iron (From Ferrous Bisglycinate Chelate- 126mg (441.000 KGS) With Other Essential Vitamins & Minerals (No of Tabs-3500000))	1 Number	1	ASCORBIC ACID DC 97 Percentage -SF. I.H	63.087 mg.	2	IRON BISGLYCINATE	122.400 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
FERROUS FORTE TABLETS((Vitamin C (as Ascorbic Acid) -71mg (248.500 KGS) +Iron (From Ferrous Bisglycinate Chelate- 126mg (441.000 KGS) With Other Essential Vitamins & Minerals (No of Tabs-3500000))	1 Number	1	ASCORBIC ACID DC 97 Percentage -SF. I.H	63.087 mg.										
		2	IRON BISGLYCINATE	122.400 mg.										

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

Case No.	54 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001167AM24
RA File Number	05AX04000581 AM24
Licence No and Date	0511019057/29/05/2023

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Tobramycin Inhalation Solution, 300mg/ 4ml	170000 Numbers	1	TOBRAMYCIN USP	56.57 kg.

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

Case No.	55 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	UNITED MUD-CHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001185AM24
RA File Number	03AX04000897 AM24
Licence No and Date	0311024056/30/05/2023

Norms Committee Decision:

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

Case No.	56 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	ENCUBE ETHICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001205AM24
RA File Number	03AX04000864 AM24
Licence No and Date	0311024068/31/05/2023

Norms Committee Decision:

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

Copy of Export Orders showing the product is exported to US.

Case No.	57 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	J B CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001206AM24
RA File Number	03AX04000854 AM24
Licence No and Date	0311024069/31/05/2023

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Aug/202323/6** dated **09/09/2022** against advance authorization **No. 0311010761** dated **21/01/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
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Nifedipine Extended-Release Tablets 30mg.(Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 56.80 mg (ii) Eastman (TMCelluloseAcetate(CA398- 10NF/EP)-33.12mg (iii)SENTRYPOLYOXWSRN80FPNF- 118.40mg.	1 Number	1	SENTRY POLYOX WSR COAGULANT NF	56.8 mg.
		2	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	33.12 mg.
		3	SENTRY POLYOX WSR N80 FP NF	118.40 mg.
Nifedipine Extended-Release Tablets 60mg.(Each tablet contains (i) Sentry Polyox WSR Coagulant NF - 113.60 mg (ii) Eastman (TMCelluloseAcetate(CA398- 10NF/EP)-42.32mg (iii)SENTRYPOLYOXWSRN80FPNF- 236.80mg	1 Number	4	SENTRY POLYOX WSR COAGULANT NF	113.60 mg.
		5	EASTMAN (TM) CELLULOSE ACETATE (CA 398-10NF/EP)	42.32 mg.
		6	SENTRY POLYOX WSR N80 FP NF	236.80 mg.

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

Case No.	58 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	ALEMBIC PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001208AM24
RA File Number	34AX04000142 AM24
Licence No and Date	3411003764/31/05/2023
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Diclofenac Sodium Topical Solution 2% 112 gm	1 Number	1	Diclofenac Sodium USP	2.2838 gm
Diclofenac Sodium Topical Gel 3 % 100 gm	1 Number	2	Diclofenac Sodium USP	3.06 gm

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

Case No.	59 / NC/3/MEET/May/202425/4																		
Case Status	Case Approved																		
Party Name	ALEMBIC PHARMACEUTICALS LIMITED																		
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024																		
HQ File Number	HQRNORM APPLY 00001209AM24																		
RA File Number	34AX04000143 AM24																		
Licence No and Date	3411003766/31/05/2023																		
Norms Committee Decision:																			
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-																			
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Fluorouracil Injection USP 2.5 gm 50 ML</td><td>1 Number</td><td>1</td><td>Fluorouracil USP</td><td>2.60 gm</td></tr><tr><td>Fluorouracil Injection USP 5 gm 100 ML</td><td>1 Number</td><td>2</td><td>Fluorouracil USP</td><td>5.20 gm</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Fluorouracil Injection USP 2.5 gm 50 ML	1 Number	1	Fluorouracil USP	2.60 gm	Fluorouracil Injection USP 5 gm 100 ML	1 Number	2	Fluorouracil USP	5.20 gm
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.															
Fluorouracil Injection USP 2.5 gm 50 ML	1 Number	1	Fluorouracil USP	2.60 gm															
Fluorouracil Injection USP 5 gm 100 ML	1 Number	2	Fluorouracil USP	5.20 gm															
RA concerned may take further necessary action as per above decision of NC.																			

Case No.	60 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	MAYA BIOTECH PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00001225AM24
RA File Number	30AX04000609 AM23
Licence No and Date	3011003608/31/05/2023
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to refer the case to Deptt. of Bio-Technology for obtaining their comments.	

Case No.	61 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	GITANJALI CHEMICALS PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00004784AM24
RA File Number	03AX04001927 AM24
Licence No and Date	0311025944/02/08/2023
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- 1. Stoichiometric material balance of the reaction on a molar basis. 2. Justification of low yield of the reaction and how to prevent side products formed during reaction. 3. The norms fixed in the past by the norms committee, for the same export and import of the item.	

Case No.	62 / NC/3/MEET/May/202425/4
Case Status	Case Deferred

Party Name	DAFFODIL PHARMACHEM PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00004908AM24
RA File Number	08AX04000865 AM24
Licence No and Date	0811009026/07/08/2023
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	63 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	AKUMS DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00006789AM24
RA File Number	05AX04002288 AM24
Licence No and Date	0511022010/09/11/2023
Norms Committee Decision:	
The committee considered the request of firm for fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:-	
UOM of export quantity may be indicated in 'Number'.	

Case No.	64 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	AKUMS DRUGS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00006849AM24
RA File Number	05AX04001479 AM23
Licence No and Date	0511021951/15/11/2023
Norms Committee Decision:	

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
MOXCOR-500mg (Amoxicillin) (Amoxicillin-500MG CAPSULES (Amoxicillin VN-21840-19)	1 Number	1	Amoxicillin Trihydrate COMP BP	585.36 mg

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

Case No.	65 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	GLENMARK PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00009345AM24
RA File Number	03AX04004079 AM24
Licence No and Date	0311029276/12/12/2023

Norms Committee Decision:

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

Export Product	Qty.	Import Items	Qty. allowed.
FLUCORT N SKIN CREAM 0.025% (Pack Size 5 gms) ((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.403 Kgs.))	322660 Packs	FLUOCINOLONE ACETONIDE BP	16.915 kg.
FLUCORT SKIN CREAM 0.025% (Pack Size 15 gms)((Net Wt.of	322660 Packs		

FLUOCINOLONE ACETONIDE BP is 1.210 Kgs.))			
FLUCORT N SKIN CREAM 0.025% (Pack Size 15 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 9.075 Kgs.))	2420000 Packs		
FLUCORT SKIN CREAM 0.025% (Pack Size 5 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 1.210 Kgs.))	968000 Packs		
FLUOCINOLONE CREAM (TDR) ET 0.025% (Pack Size 10 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.))	96800 Packs		
CYNOZET CREAM 0.025% (Pack Size 5 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.))	193600 Packs		
CYNOZET CREAM 0.025% (Pack Size 15 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.))	64532 Packs		
SUPRICORT CREAM 0.025% (Pack Size 5 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.726 Kgs.))	580800 Packs		
SUPRICORT CREAM 0.025% (Pack Size 15 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.726 Kgs.))	193596 Packs		
SUPRICORT CREAM 0.025% (Pack Size 250 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.))	3873 Packs		
SUPRICORT N CREAM 0.025% (Pack Size 5 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.))	193600 Packs		

SUPRICORT N CREAM 0.025% (Pack Size 15 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.242 Kgs.))	64532 Packs		
Flucort C Cream 0.01% (Pack Size 15 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.095 Kgs))	63332 Packs		
FLUCORT C OINTMENT 0.025% (Pack Size 15 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.605 Kgs.))	161330 Packs		
GLENCORT GEL 0.025 % (Pack Size 5 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.452 Kgs.))	361600 Packs		
GLENCORT GEL 0.025 % (Pack Size 30 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.484 Kgs.))	64535 Packs		
FLUCORT MZ SKIN OINTMENT 0.01% (Pack Size 15 gms)((Net Wt.of FLUOCINOLONE ACETONIDE BP is 0.145 Kgs.))	96798 Packs		
RA concerned may take further necessary action as per above decision of NC.			

Case No.	66 / NC/3/MEET/May/202425/4
Case Status	Case Rejected
Party Name	EAST AFRICAN INDIA OVERSEAS
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM REVIW00000462AM25
RA File Number	05AX04003662 AM24
Licence No and	0511024074/26/02/2024

Date	
Norms Committee Decision: The Committee considered the request of firm for review of ad-hoc norms and it was observed that the firm has not provided any technical justification / information for enhancement. Hence, it was decided to reject the case maintaining the status quo.	

Case No.	67 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	VIMAGE PARENTERAL LLP
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008849AM24
RA File Number	50AX04000104 AM24
Licence No and Date	5011001310/01/03/2024
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	68 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	SWISS PARENTERALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008851AM24
RA File Number	08AX04002088 AM24
Licence No and Date	0811010935/01/03/2024
Norms Committee Decision: The case is under consideration for want of comments of TE.	

Case No.	69 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	SHARP MINT LIMITED

Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008852AM24
RA File Number	05AX04003809 AM24
Licence No and Date	0511024175/01/03/2024
Norms Committee Decision: The committee considered the request of firm for review/fixation of ad-hoc norms and as per the advise of the TE, it was decided to call for following information/documents from the firm:- - Step wise manufacturing process. - Complete chemical reactions with molecular and structural formula and molecular weights along with stage wise percentage yields on molar basis. - Complete technical details as per Annexure to Appendix 4E for chemical products. - Stoichiometric balance between import and export on molar basis. - Details of indigenous input with quantity.	

Case No.	70 / NC/3/MEET/May/202425/4										
Case Status	Case Approved										
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024										
HQ File Number	HQRNORM APPLY 00008878AM24										
RA File Number	08AX04002161 AM24										
Licence No and Date	0811010941/02/03/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Fen/202324/23 dated 19/02/2024 against advance authorization No. 0811009509 dated 03/10/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Phenylephrine Hydrochloride Injection USP, 10 mg/mL (10 mL)</td><td>1 Number</td><td>1</td><td>Phenylephrine HCl USP/Ph.Eur</td><td>110.00 mg/vial</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Phenylephrine Hydrochloride Injection USP, 10 mg/mL (10 mL)	1 Number	1	Phenylephrine HCl USP/Ph.Eur	110.00 mg/vial
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Phenylephrine Hydrochloride Injection USP, 10 mg/mL (10 mL)	1 Number	1	Phenylephrine HCl USP/Ph.Eur	110.00 mg/vial							

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

Case No.	71 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	MICRO LABS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008891AM24
RA File Number	07AX04001899 AM24
Licence No and Date	0711010690/04/03/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Mar/202223/24 dated 13/04/2023** against advance authorization **No.0711003428 dated 15/03/2022**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Chlordiazepoxide Hydrochloride and Clidinium Bromide Capsules 5mg/2.5 mg (15.75 kgs))	1 Number	1	Chlordiazepoxide Hydrochloride BP/EP/USP/IP	5.1 mg.
		2	Clidinium Bromide BP/EP/USP/IP	2.55 mg

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

Case No.	72 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008892AM24

RA File Number	08AX04002171 AM24			
Licence No and Date	0811010967/04/03/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jan/202324/21 dated 24/01/2024 against advance authorization No.0811008135 dated 10/05/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
PROPAFENONE TABLETS 150MG (PROPRAFENON150HEUMANN) (EACH FILM COATED TABLET CONTAINS: PROPAFENONE HYDROCHLORIDE PH. EUR. 150 MG	1 Number	1	PROPAFENONE HYDROCHLORIDE EP	153 mg/ tablet
PROPAFENONE TABLETS 300MG (PROPRAFENON 300 HEUMANN) (EACH FILM COATED TABLET CONTAINS:PROPAFENONE HYDROCHLORIDE PH. EUR. 300 MG	1 Number	2	PROPAFENONE HYDROCHLORIDE EP	306 mg/ tablet
RA concerned may take further necessary action as per above decision of NC.				

Case No.	73 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008890AM24
RA File Number	05AX04003801 AM24
Licence No and Date	0511024319/04/03/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export	

product/import product in meeting **No.NC/3/MEET/Dec/202324/19** dated **05/01/2024** against advance authorization **No.1311000462** dated **22/07/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Meropenem for Injection	1 kg.	1	Meropenem Trihydrate (Non Sterile)	0.8968 kg.

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

Case No.	74 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	ASTEC LIFESCIENCES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008899AM24
RA File Number	03AX04005541 AM24
Licence No and Date	0311031703/05/03/2024

Norms Committee Decision:

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

- 1. To give nomenclature of each reactant and product formed in reaction, without using abbreviation.**
- 2. Justification of low yield of the reaction.**
- 3. The norms fixed in the past by the norms committee, for the same export and import of the items.**
- 4. End use of export item.**

Case No.	75 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	RAJASTHAN ANTIBIOTICS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008919AM24
RA File Number	05AX04003769 AM24
Licence No and Date	0511024342/06/03/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Piperacillin Sodium and Tazobactam Sodium Sterile (8:1)	1 kg.	1	Tazobactam Acid	0.1075 kg.
			Piperacillin Acid	0.890 kg.

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

Case No.	76 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008936AM24
RA File Number	52AX04000378 AM24
Licence No and Date	5211007594/06/03/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty.
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				allowed.
CLOBETASOL PROPIONATE CP	1 kg.	1	BETAMETHASONE	1.00 kg.

Note: The committee decided to fix the SION for inpute ‘Clobetasol Propionate’.

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

Case No.	77 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	SRI KRISHNA PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008937AM24
RA File Number	09AX04001083 AM24
Licence No and Date	0911006881/06/03/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	78 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	RITSA PHARMA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008938AM24
RA File Number	09AX04001035 AM24
Licence No and Date	0911006882/06/03/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	79 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	AUORE LIFE SCIENCES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008940AM24
RA File Number	09AX04001061 AM24
Licence No and Date	0911006884/06/03/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	80 / NC/3/MEET/May/202425/4			
Case Status	Case Approved			
Party Name	MICRO LABS LIMITED			
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024			
HQ File Number	HQRNORM APPLY 00008957AM24			
RA File Number	07AX04001905 AM24			
Licence No and Date	0711010708/07/03/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jan/202324/20 dated 18/01/2024 against advance authorization No.0711007283 dated 06/04/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DIRECT COMPRESSION GRANULES OF PHLOROGLUCINOL 160MG ODT PREMIX(DIRECT COMPRESSION GRANULES OF PHLOROGLUCINOL 160MG ODT	1 kg.	1	PHLOROGLUCINOL DIHYDRATE Ph.EUR	0.359 kg.

PREMIX (EACH 450mg Premix Contains 160mg Phloroglucinol) contents 224.28 kg)				
RA concerned may take further necessary action as per above decision of NC.				

Case No.	81 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008946AM24
RA File Number	52AX04000379 AM24
Licence No and Date	5211007605/07/03/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Jun/202324/8 dated 30/06/2023** against advance authorization **No. 5211004531 dated 31/03/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRIAMICINOLONE IP/EP/BP/USP	1 kg.	1	3,20-DIOXOPREGNA-1,4,9(11),16 - TETRAEN - 21-YLACETATE (3 TR)	1.00 kg.

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

Case No.	82 / NC/3/MEET/May/202425/4
Case Status	Case Approved

Party Name	SANJIVANI PHARMA										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024										
HQ File Number	HQRNORM APPLY 00008951AM24										
RA File Number	34AX04000872 AM24										
Licence No and Date	3411004694/07/03/2024										
Norms Committee Decision: The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:- <table border="1"> <thead> <tr> <th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr> </thead> <tbody> <tr> <td>Clobetasol 17 Propionate</td><td>1 kg.</td><td>1</td><td>Betamethasone</td><td>1.00 kg.</td></tr> </tbody> </table> Note: The committee decided to fix the SION for input 'Clobetasol Propionate'. RA concerned may take further necessary action as per above decision of NC.		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Clobetasol 17 Propionate	1 kg.	1	Betamethasone	1.00 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Clobetasol 17 Propionate	1 kg.	1	Betamethasone	1.00 kg.							

Case No.	83 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	AVIK PHARMACEUTICAL LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008953AM24
RA File Number	52AX04000377 AM24
Licence No and Date	5211007606/07/03/2024
Norms Committee Decision: The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Jun/202324/8 dated 30/06/2023 against advance authorization No. 5211004531 dated 31/03/2023, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TRIAMICINOLONE ACETONIDE IP/EP/BP/USP	1 kg.	1	3,20-DIOXOPREGNA- 1,4,9(11),16 - TETRAEN - 21- YLACETATE (3 TR)	1.00 kg.

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

Case No.	84 / NC/3/MEET/May/202425/4													
Case Status	Case Approved													
Party Name	MANKIND PHARMA LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024													
HQ File Number	HQRNORM APPLY 00008965AM24													
RA File Number	05AX04003839 AM24													
Licence No and Date	0511024393/07/03/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Mar/202324/26 dated 22/03/2024 against advance authorization No. 0511023265 dated 15/01/2024 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Tobramycin Inhalation Solution, 300mg/ 5ml</td><td>1 Number</td><td>1</td><td>TOBRAMYCIN USP</td><td>306 mg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Tobramycin Inhalation Solution, 300mg/ 5ml	1 Number	1	TOBRAMYCIN USP	306 mg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Tobramycin Inhalation Solution, 300mg/ 5ml	1 Number	1	TOBRAMYCIN USP	306 mg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	85 / NC/3/MEET/May/202425/4										
Case Status	Case Approved										
Party Name	JUBILANT GENERICS LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024										
HQ File Number	HQRNORM APPLY 00008966AM24										
RA File Number	05AX04003851 AM24										
Licence No and Date	0511024394/07/03/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Feb/202324/23 dated 19/02/2024 against advance authorization No. 3411004140 dated 21/09/2023 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Amantadine HCL 100mg</td><td>1 Number</td><td>1</td><td>Amantadine Hydrochloride</td><td>102.00 mg./Tablet</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Amantadine HCL 100mg	1 Number	1	Amantadine Hydrochloride	102.00 mg./Tablet
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
Amantadine HCL 100mg	1 Number	1	Amantadine Hydrochloride	102.00 mg./Tablet							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	86 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	MANKIND PHARMA LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00008983AM24
RA File Number	05AX04003903 AM24
Licence No and Date	0511024411/08/03/2024
Norms Committee Decision:	

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

1. **Copy of Master Batch Formula (MBF).**
2. **Copy of Drug Manufacturing Licence (DML).**

Case No.	87 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	LEBEN LABORATORIES PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00009001AM24
RA File Number	03AX04005652 AM24
Licence No and Date	0311031952/11/03/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
DOXYLEB CAPSULE (DOXYCYCLINE HYCLATE CAPSULE BP) 100MG(IN PACKING OF 10X10'S, 10X100'S & 1000'S. QTY CONSUMED OF EXEMPT MATERIAL DOXYCYCLINE HYCLATE BP- 115.400MG/CAPSULE)	1 Number	1	DOXYCYCLINE HYCLATE BP	115.40 mg.

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

Case No.	88 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00009016AM24
RA File Number	03AX04005612 AM24
Licence No and Date	0311031972/11/03/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	89 / NC/3/MEET/May/202425/4				
Case Status	Case Approved				
Party Name	ANNORA PHARMA PRIVATE LIMITED				
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024				
HQ File Number	HQRNORM APPLY 00009019AM24				
RA File Number	09AX04000658 AM23				
Licence No and Date	0911004281/11/03/2024				
Norms Committee Decision:					
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-					

Case No.	90 / NC/3/MEET/May/202425/4													
Case Status	Case Approved													
Party Name	MAXMED LIFE SCIENCES PRIVATE LIMITED													
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024													
HQ File Number	HQRNORM APPLY 00009025AM24													
RA File Number	05AX04003876 AM24													
Licence No and Date	0511024356/11/03/2024													
Norms Committee Decision:														
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-														
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>Amoxycillin oral suspension (Amoxycillin Syrup) 250 mg/5 ml, 60 ml bottle (Each 5 ml contains Amoxycillin Trihydrate equivalent to 250 mg of Amoxycillin))</td><td>1500000 Numbers</td><td>1</td><td>Amoxycillin Trihydrate</td><td>5423.0 kg.</td></tr></table>					Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	Amoxycillin oral suspension (Amoxycillin Syrup) 250 mg/5 ml, 60 ml bottle (Each 5 ml contains Amoxycillin Trihydrate equivalent to 250 mg of Amoxycillin))	1500000 Numbers	1	Amoxycillin Trihydrate	5423.0 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.										
Amoxycillin oral suspension (Amoxycillin Syrup) 250 mg/5 ml, 60 ml bottle (Each 5 ml contains Amoxycillin Trihydrate equivalent to 250 mg of Amoxycillin))	1500000 Numbers	1	Amoxycillin Trihydrate	5423.0 kg.										
RA concerned may take further necessary action as per above decision of NC.														

Case No.	91 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	FREESIA CHEMICALS
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00009031AM24
RA File Number	03AX04005613 AM24
Licence No and Date	0311032018/12/03/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export	

product/import product in meeting **No. NC/3/MEET/Mar/202324/26 dated 22/03/2024** against advance authorization **No. 0311029806 dated 01/01/2024**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Cyclopentanone(CAS NO. 120-92-3)	1 kg.	1	Adipic Acid	1.93 kg.

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

Case No.	92 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00009059AM24
RA File Number	03AX04005628 AM24
Licence No and Date	0311032047/12/03/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	93 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	TORRENT PHARMACEUTICALS LTD
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00009032AM24
RA File Number	08AX04002174 AM24
Licence No and Date	0811010987/12/03/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No.NC/3/MEET/Sep/202324/14 dated 27/09/2023 against advance	

authorization No. **0811009097** dated **16/08/2023**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
ISOSORBIDE MONONITRATE EXTENDED RELEASE TABLETS USP 60 MG (EACH FILM COATED EXTENDED RELEASE TABLETS CONTAINS: DILUTED ISOSORBIDE MONONITRATE (50% DILUTED WITH LACTOSEMONOHYDRATE) USPEQUIVALENT TO ISOSORBIDE MONONITRATE 60 MG,	1 Number	1	Isosorbide Mononitrate 50 percent Assay. Diluted ISMN (50% diluted with lactose monohydrat e) USP	122.40 mg
ISOSORBIDE MONONITRATE EXTENDED RELEASE TABLETS USP 120 MG(EACH FILM COATED EXTENDED RELEASE TABLETS CONTAINS: DILUTED ISOSORBIDE MONONITRATE (50% DILUTED WITH LACTOSEMONOHYDRATE) USP EQUIVALENT TO ISOSORBIDE MONONITRATE 120 MG,	1 Number	2	Isosorbide Mononitrate 50 percent Assay. Diluted ISMN (50% diluted with lactose monohydrat	244.80 mg.

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

Case No.	94 / NC/3/MEET/May/202425/4
Case Status	Case Deferred
Party Name	AMNEAL PHARMACEUTICALS PRIVATE LIMITED
Meeting Number	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024

and Date	
HQ File Number	HQRNORM APPLY 00009076AM24
RA File Number	08AX04002209 AM24
Licence No and Date	0811011004/13/03/2024
Norms Committee Decision:	
The case is under consideration for want of comments of TE.	

Case No.	95 / NC/3/MEET/May/202425/4										
Case Status	Case Approved										
Party Name	SALVI CHEMICAL INDUSTRIES LIMITED										
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024										
HQ File Number	HQRNORM APPLY 00009083AM24										
RA File Number	03AX04005645 AM24										
Licence No and Date	0311032129/13/03/2024										
Norms Committee Decision:											
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-											
<table><tr><th>Export Product</th><th>Qty.</th><th>Sl. No.</th><th>Import Items</th><th>Qty. allowed.</th></tr><tr><td>HALQUNOL BP 80</td><td>1 kg.</td><td>1</td><td>8 HYDROXY QUINOLINE</td><td>0.77 kg.</td></tr></table>		Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.	HALQUNOL BP 80	1 kg.	1	8 HYDROXY QUINOLINE	0.77 kg.
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.							
HALQUNOL BP 80	1 kg.	1	8 HYDROXY QUINOLINE	0.77 kg.							
RA concerned may take further necessary action as per above decision of NC.											

Case No.	96 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	MANGALAM DRUGS AND ORGANICS LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00009085AM24
RA File Number	03AX04005648 AM24

Licence No and Date	0311032134/14/03/2024			
Norms Committee Decision:				
The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting No. NC/3/MEET/Mar/202122/16 dated 08/04/2022 against advance authorization No. 0311008136 dated 01/11/2021 , it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-				
Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
LUMEFANTRINE	1 kg.	1	FLUORENE	0.90 kg.
		2	DIMETHYL FORMAMIDE (DMF)	0.555 kg.
		3	DI N BUTYLAMINE (N-DBA)	0.50 kg.
		4	4-CHLOROBENZALDEHYDE	0.3476 kg.
		5	SODIUM BOROHYDRIDE	0.060 kg.
RA concerned may take further necessary action as per above decision of NC.				

Case No.	97 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	ZENTIVA PRIVATE LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00009106AM24
RA File Number	03AX04005708 AM24
Licence No and Date	0311032153/14/03/2024
Norms Committee Decision:	
The Committee considered the case as per agenda and it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-	

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Co-dydramol 10/500 tablets (Dihydrocodeine Tartrate 10mg and Paracetamol 500mg Tablets)(Each Tablet contains Dihydrocodeine Tartrate 10mg and Paracetamol 500mg	1 Number	1	Dihydrocodeine Tartrate	10.2 mg

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

Case No.	98 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	SUN PHARMACEUTICAL INDUSTRIES LIMITED
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00009140AM24
RA File Number	05AX04003925 AM24
Licence No and Date	0511024521/15/03/2024

Norms Committee Decision:

The Committee considered the case as per agenda and taking cue from the earlier decision for same export product/import product in meeting **No.NC/3/MEET/Apr/202223/1 dated 29/04/2022** against advance authorization **No. 0511006574 dated 02/12/2021**, it was decided to fix ad-hoc norms under Para 4.07 of HBP Vol. I as per details given below or as applied by the firm, whichever is less:-

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Nepafenac Ophthalmic Suspension, 0.1% w/v Sterile Eye Drops, 5ml) ((Each ml contains Nepafenac 1.0 mg (Equivalent to 450.000 Gram of Bulk Drug))	90000 Numbers	1	Nepafenac	459 gm.

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

Case No.	99 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	NEULAND LABORATORIES LTD.
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024
HQ File Number	HQRNORM APPLY 00009315AM24
RA File Number	09AX04001149 AM24
Licence No and Date	0911006981/26/03/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
Benzyl (1S,2R,3R,4aR,6aS,7R,8R,10aR,10bR,12aR)- 3-hydrazineyl-2-hydroxy-1,6a,8,10a- tetramethyl-8-((R)-3-methylbutan. (-2- yl)- 1,3,4,6,6a,7,8,9,10,10a,10b,11,12,12a- tetradecahydro-2H-1,4a- (methanooxymethano)chrysene-7- carboxylate(Drug Intermediate of Ibexafungerp Citrate))	1 kg.	1	ENFUMAFUNGIN	2.086 kg.

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

Case No.	100 / NC/3/MEET/May/202425/4
Case Status	Case Approved
Party Name	SHREE MAHADEV INTERMEDIATE
Meeting Number and Date	NC/ 3/ MEET/ May/ 202425/ 4 and 06/06/2024

HQ File Number	HQRNORM APPLY 00000037AM25
RA File Number	34AX04000967 AM24
Licence No and Date	3411004750/02/04/2024

Norms Committee Decision:

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

Export Product	Qty.	Sl. No.	Import Items	Qty. allowed.
TETRAHYDRODICYCLOPENTADIENE IN HEXANE SOLUTION (97.4% purity)	1 kg.	1	DICYCLOPENTADIENE	0.995 kg.

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